Life & Health

Rapid Protocol Training Solution

IMPROVE CLINICAL SITE READINESS AND ACCELERATE SUBJECT ENROLLMENT

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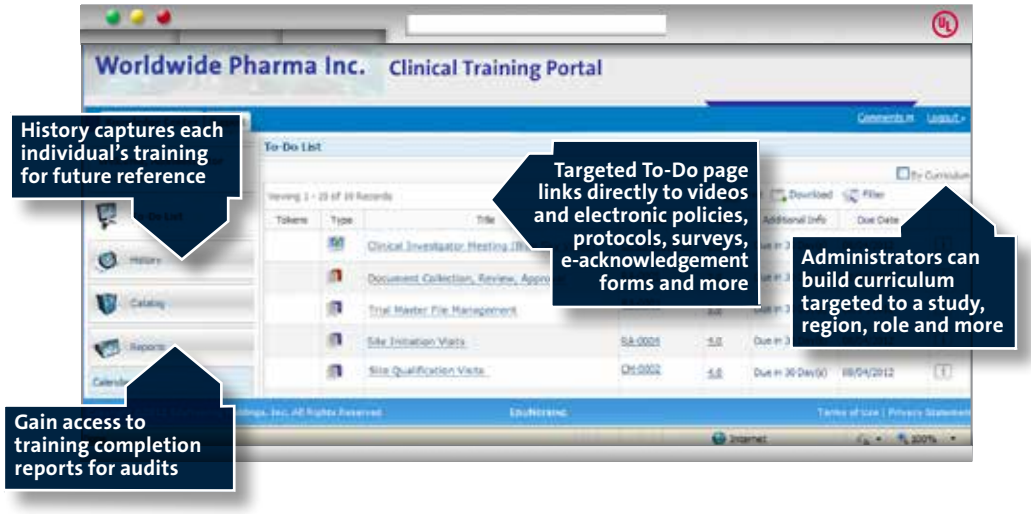
As a clinical site manager, you have to assure that global investigators and study staff are trained, while accelerating study startup times and minimizing costs.

That's a tremendous challenge, but one that many Life Science companies are accomplishing through virtual clinical training tools, such as ComplianceWire,® UL EduNeering's award-winning platform, custom and standard protocol-specific content, and "virtual" investigator meetings. All activities are delivered and tracked via the ComplianceWire system.

Leverage the Same Platform Used by the US FDA to Train Global Inspectors

The UL solution can serve as a stand-alone training platform or integrate with your existing site portal, enabling you to deliver recorded investigator meetings as well as study materials to internal study teams, clinical sites, Institutional Review Boards (IRBs) and third party service providers around the world.

The FDA and other global regulatory agencies require that materials are delivered in a secure manner. ComplianceWire is the system that powers the FDA's online university, used to train federal, state and local as well as GxP, inspection and enforcement, and clinical research requirements.



The "Ready to Use" Training Solution that You Can Deploy in Weeks... Not Months

Sponsors and CROs that demand rapid delivery of protocols and other critical study materials are relying on ComplianceWire and our integration with Blue Sky Broadcast, to deliver and capture virtual investigator meetings, as well as electronic documents and e-acknowledgements without spending months developing a training portal from the ground up.

Customize Your Training Site

With ComplianceWire, you can apply company branding to your training site, and provide single sign-on access from any existing clinical portal. In addition, the site features secure administrator access so you can segment site personnel by studies and roles, and deliver the right materials to the right individuals.

Real-time reporting is an integral part of this 21 CFR Part 11-compliant system.

Demonstrate to the FDA that Investigators and Monitors Have Been Trained:

According to the FDA, Section 312.53 (a) and (d):

- A sponsor shall select only investigators qualified by training and experience as appropriate experts to investigate the drug.
- A sponsor shall select a monitor qualified by training and experience to monitor the progress of the investigation.

Key Benefits of UL's Rapid Protocol Training Solution:

- Leverages Cloud Computing Model.
- Designed to Meet the Security and Data Integrity Requirements of FDA-Regulated Organizations.
- Ability to Organize Multiple Types of Clinical Study Content into well-defined curricula:
  - GCP training
  - Investigator Meetings (Video Recordings and Virtual Events)
  - Therapeutic/indication presentations (Video Recordings and Virtual Events)
  - Protocols and related amendments
  - SOPs
  - eClinical operational training (online courses and guides)
  - Internal procedure documents
  - Clinical best practice documents
- Deliver and Track Training Content and Assessments to All Clinical Personnel:
  - Investigators
  - Internal Study Team
  - CRAs
  - CRCs
  - Medical Monitors
  - Data Managers

Powerful Tools for Delivering – and Documenting – Study Knowledge to Sites

Today's study-specific training must reduce the time spent on site initiation and site certification without compromising the quality of the educational experience or the integrity of the documented receipt that these activities were completed successfully. And if a site experiences turnover, this requirement becomes more critical.

ComplianceWire and our Learning Services team enables site management teams to ensure that Good Clinical Practice (GCP) compliance and study conduct, as well as clinical operations training, are performed in a high quality manner. Our rapid clinical training solution offers these benefits:

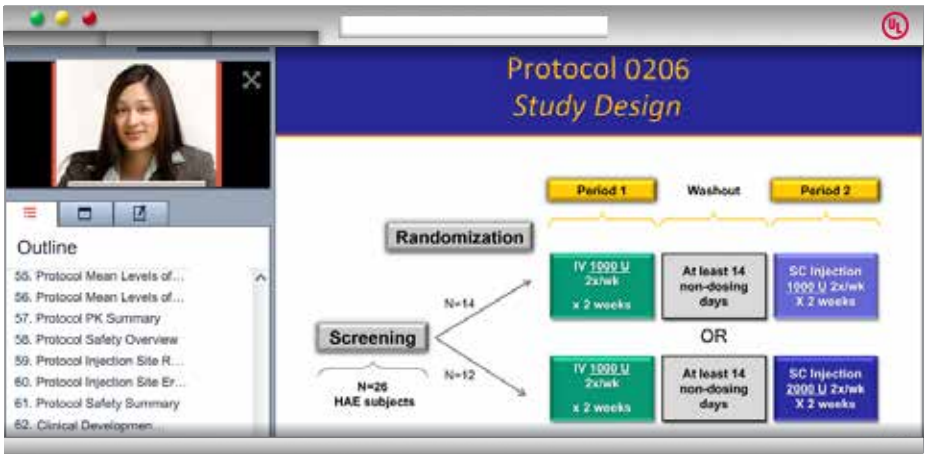
- **A Secure, Proven Platform:** Clients leverage the same web-based global training platform used by the FDA to train inspectors globally.
  - You can define specific roles within the study: investigators, Clinical Research Associates (CRAs), Investigational Review Boards (IRBs), etc. to receive targeted training.
  - ComplianceWire was designed to meet the stringent security requirements of 21 CFR Part 11 so all electronic signatures are captured for audit purposes, and you don't have to struggle with internal firewall issues.

- **Off the Shelf Clinical Courses:** UL's self-paced, computer-based training focuses on GCP topics and role-based operational training; we also feature the innovative Global Clinical Library content from the Duke Clinical Research Institute (DCRI).
  - Our Learning Services team can develop custom courses focused on technology operations, Electronic Data Capture (EDC), Interactive Voice Response System (IVRS), etc., for engaging instructional modules that walk site personnel through the process.
- **Ability to Capture Live Investigator Meetings:** You can leverage our integration with Blue Sky Broadcast and have your investigator meetings videotaped and stored for delivery at a later date (dubbing or subtitles are also available); you can also use our optional EduConnect tool to schedule and capture attendance of meetings, disease state presentations and product usage demonstrations, so they can be delivered as prescribed training to learners, with assessments if necessary, so learners can demonstrate they have retained the material.
- **Target Content by Role Within a Study or Sponsor:** Through ComplianceWire, you can define specific roles within the study: investigators, CRAs, IRBs, etc. to receive targeted training (see graphic below).
- **Build Assessments Easily, Without Additional Programming:** Learners can review all electronic documents online, then complete assessments to demonstrate receipt and understanding.
- **Gain Feedback from Site Personnel:** Individuals can provide constant feedback through assessments and surveys for fast response and performance training to address knowledge gaps.
- **Build Risk-Based Assessments:** You can deliver online assessments to clinical site personnel that will determine the type of training they need based on their job function, and identify "high-risk" activities that can receive additional communication.

Our Off-the-Shelf Clinical Courses Include Titles Such as:

- Aspects of Regulatory History
- Bioresearch Monitoring (BIMO): Introduction
- Clinical Trial Audits and Consequences of Noncompliance
- Drug Safety and Adverse Event Reporting
- European Union Clinical Trials Directive
- Good Clinical Practices (GCPs) for New Product Investigations
- HIPAA – The Impact On Clinical Research
- Informed Consent
- Medical Device Safety Reporting
- Overview of the Clinical Research Process
- Protection of Human Subjects in Clinical Trials
- Recruitment and Retention of Study Patients

How to Capture Live Events for All Site Personnel



Maximizing Your Investment in Investigator Meetings: During investigator meetings, some of our clients have reported that only 50% or so of participating investigators can attend in person. What's worse, investigators who do attend these meetings often ask for supplementary material following the site initiation phase. It's clear that the material provided during an investigator meeting needs to add value through site initiation and beyond.

Transform Videos into Reference Material:
Through our affiliation with Blue Sky Broadcast, UL solves this challenge, as we can video record investigator meetings so investigators can view the live meeting remotely. In a similar way, disease state and protocol presentations can be recorded, saved on UL's secure servers, and made available to site personnel who can watch as many times as needed. You can also have assessments appear for the learner to demonstrate their knowledge before they electronically sign.

Target the Right Training to the Right Role: UL enables you to set up groups of learners within a study, and as a role. You gain maximum flexibility in assigning the right training to the right individuals, whether it's guidelines for all site personnel, spanning multiple studies or study-specific materials for a just a few data managers. For Contract Research Organizaitons (CROs), ComplianceWire enables you to organize studies by sites, and securely separate training profiles when generating audit reports for each sponsor.

Integration with Clinical Systems: Our clinical training platform can be easily integrated with your Clinical Training Management System (CTMS) and other clinical databases, as well as document management systems, ensuring that qualification information can be used to prevent site personnel from participating in the trial until they've completed the training program.

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.

The CREATe Program, Powered by Duke Clinical Research Institute:

Our affiliation 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 are self-paced and 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.

We invite you to demo our Rapid Protocol Training solutions for yourself. Find out why more than 300 companies trust ComplianceWire to deliver qualification-focused content and assessments to more than one million individuals worldwide.

To learn more, contact Pat Thunell at **609-627-5302** or pat.thunell@ul.com.

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