Clinical Site Qualification Solution

IMPROVE CLINICAL SITE READINESS AND ACCELERATE SUBJECT ENROLLMENT

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Sponsors often struggle to qualify global investigators and study staff with protocol and non-protocol education, while accelerating study startup times and minimizing costs. The key to success is "embedding" clinical qualification into the clinical IT infrastructure, so that site managers gain visibility from the clinical systems they use most often.

That's why many companies trust ComplianceWire,® to deliver and track both protocol-specific and non-protocol content, including "virtual" investigator meetings.

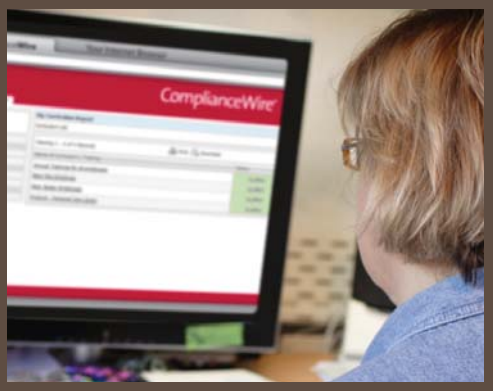
Leverage the Same Platform Used by the US FDA to Train Global Inspectors

While ComplianceWire can serve as a "stand-alone" system to capture certification and qualification, clients can also choose to integrate the system within their Clinical Trial Management System, so that a "qualified" indicator is recorded when personnel complete investigator meetings, read protocols, and even complete GCP training or EDC or similar operational activities.

The FDA and other global regulatory agencies require that materials are delivered in a secure manner. UL's ComplianceWire is the system that powers the FDA's online university used by the agency to train federal, state and local investigators on GxP, inspection and enforcement.

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

ComplianceWire can be the system of record for all protocols and other critical study materials such as recorded investigator meetings, as well as electronic documents and e-acknowledgements. Because the system is easy to configure for each client, a typical setup can take about six to eight weeks.



Integrate with your CTMS

With ComplianceWire, you can use APIs to integrate the system into your clinical ecosystem. 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.

Data integrity is assured through ComplianceWire, as the system was designed to meet 21 CFR Part 11 requirements.

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.

Protocol and Non-Protocol Items, Sorted by Role

- **Non-Protocol-Related Items**
  - GCP training
  - Ability to grant credits for third-party training completions
  - SOPs
  - eClinical operational training (online courses and guides)
  - Internal procedure documents

- **Protocol-Related Items**
  - Investigator Meetings (Video Recordings and Virtual Events)
  - Therapeutic/indication presentations (Video Recordings and Virtual Events)
  - Protocols and related amendments
  - eClinical operational training (online courses and guides)
  - Internal brochure
  - Clinical best practice documents

- **Groups Sorted by Clinical Personnel:**
  - Investigators
  - Internal Study Team
  - CRAs

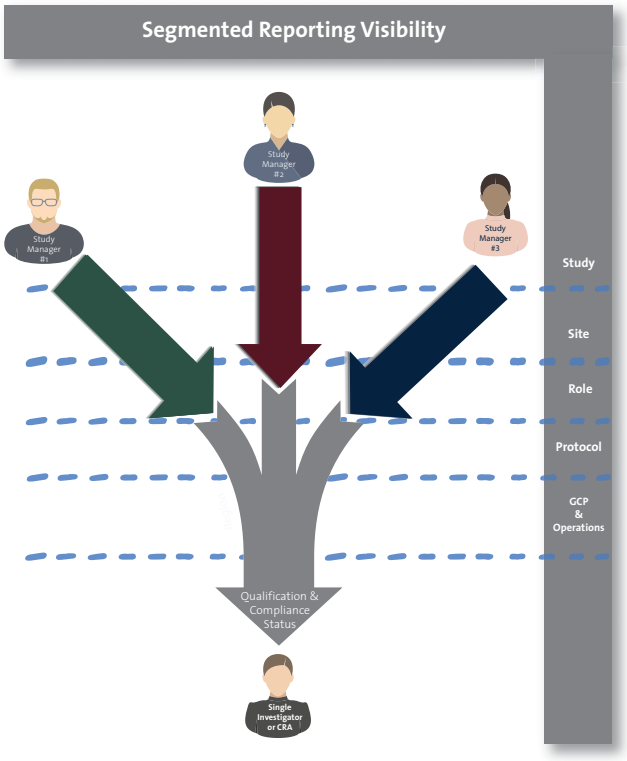
Linking Site Managers to Specific Study Personnel

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.

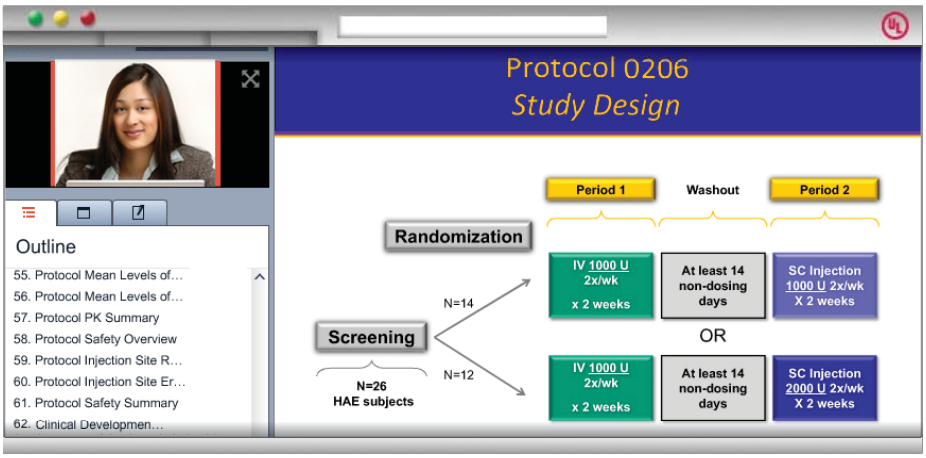
- Off the Shelf Clinical Courses: UL's self-paced, computer-based training focuses on GCP topics and role-based operational training. A course image is presented below. Further, UL's Learning Services team develops custom courses focused on technology operations, Electronic Data Capture (EDC), Interactive Voice Response System (IVRS), etc., for engaging instruction that walk site personnel through the process.
- Ability to Capture Live Investigator Meetings: UL can help you video record meetings and deliver them to site personnel (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). Our unique domain security enables each clinical site manager to gain segmented visibility of site personnel based on the role, region, study and site attributes associated with each clinical professional.
- 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.



With innovative Domain Security functionality in ComplianceWire, site managers only gain visibility into site personnel activities that are mapped to a specific site, region, study or role, while GCP and operational qualification is visible to all study managers.

Deliver convenient, self-paced GCP education designed for investigators, CRAs, and CRCs.

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:
UL works with leading video companies to 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 Qualifications 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. ComplianceWire enables sponsors to organize studies by sites, and securely separate individual profiles when generating audit reports based on the specific study.

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 Compliance to Performance

UL Compliance to Performance provides knowledge and expertise that empowers Life Sciences organizations globally to accelerate growth and move from compliance to performance. Our solutions help companies enter new markets, manage compliance, optimize quality and elevate performance by supporting processes at every stage of a company's evolution. UL provides a powerful combination of advisory solutions with a strong modular SaaS backbone that features ComplianceWire®, our award-winning learning and performance platform.

UL is a premier global independent safety science company that has championed progress for 120 years. More than 12,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

Learn more about our clinical solutions and why hundreds of organizations trust UL to manage their clinical qualifications globally.

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