Qualifying Clinical Site Personnel Using Embedded Automation

Four Guiding Rules for Embedding an eClinical Qualification Solution

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As clinical trials continue to expand globally, technology plays a critical role in maintaining data integrity and at the same time accelerating study start-up. Consider a study management team that must travel globally to hold investigator meetings. Given that clinical trials in Asia had experienced 30% average annual growth from 2005 to 2012[1], travel takes up a much greater portion of the study management team's time and energy.

That's why study teams have turned to technology to reduce this effort – from preclinical R&D and regulatory communication to packaging/distribution and postmarketing studies.

To be successful, site personnel qualification technology must be targeted to each role within the clinical research site. Otherwise, each individual within the site would receive too much or not the right material that pertains to their function within the study.

As a provider of clinical site qualification technologies to the Life Sciences industry, UL Compliance to Performance has identified four guiding rules for structuring an automated Clinical Qualification solution within a company's clinical system architecture, so that it delivers the following benefits:

- Improves the role-based performance of clinical site personnel;
- Improves the acumen and performance of investigators;
- Accelerates ramp-up time for new sites;
- Demonstrates commitment to a well-trained staff during sponsor audits;
- Reduces the time related to audit preparation during regulatory audits;
- Reduces overall site personnel qualification costs;
- Assures compliance with protocol and non-protocol requirements.

By using technology to manage both employee training as well as site personnel training, study teams can demonstrate a global commitment to quality and compliance.

1. Globalization of clinical trials: ethical and regulatory implications, International Journal of Clinical Trials , da Silva RE et al. Int J Clin Trials. 2016 Feb;3(1):1-8

eClinical's Role in Clinical Site Performance

Clinical trials have the potential to represent the costliest and most time-consuming phase of product development. One study can include hundreds of patients and multiple sites, and sponsors are challenged to accelerate site initiation.

Traditionally, the process of training employees and site personnel on GCP fundamentals, study protocols and even EDC (electronic data capture) technology was conducted using an in-person approach. However, this approach can be costly as employees and sites become more dispersed. This approach also causes a heavy administrative burden in "capturing" training and qualification records, for auditing purposes.

Sponsors seeking an eClinical qualification solution need to consider integration tools, online forms, eLearning and the ability to capture instructor-led training, such as investigator meetings. For example, UL clients have relied on ComplianceWire®, a secure web-based system that enables sponsors and CROs to add eClinical training for both employees and clinical research sites:

1. Distribute and capture "read and understood" records related to site personnel for all protocol-related materials;
2. Administer online GCP training courses, SOPs, and other non-protocol items;

With eClinical Qualification programs embedded in the clinical ecosystem (which includes CTMS, EDC, etc.), clients have reported on average a 40% or greater reduction in site initiation training costs. At the same time, clients have reported that both employees and site personnel have demonstrated improved proficiency within studies.

The eClinical qualification solution must have the potential to reduce the risks of noncompliance. While much attention focuses on the costs of patient and investigator recruitment on clinical trials, noncompliance with regulatory requirements represents one of the most significant – and unnecessary – risks to a clinical study's research integrity and bottom line.

Inadequate knowledge among clinical investigators and support staff, investigational review boards, and corporate compliance personnel can delay clinical studies and postpone product approval by regulators. eClinical documents compliant with clinical research materials enable CROs and service providers to measure effectiveness using real data, rather than in-person training observation only.

KEY TOPICS

Defining the Goals of an eClinical Qualification Solution

Regardless of a study's location, the sale of the medical products in the US requires FDA approval of study results and compliance with FDA-mandated standards of knowledge, critical information management and documentation.

Study teams have detailed their compliance and business goals:

1. Provide timely and consistent updates of critical study information to project teams as well as external study teams.
2. Gain assurances that the study and product information was received and understood by the responsible person.
3. Start or complete post-marketing commitments on time.

While these goals may differ across the clinical industry, it's critical that the eClinical qualification solution fulfill the company's goals and demonstrate value to both employees and site personnel, while demonstrating a strong ROI to senior managers in Quality and Finance. To map out eClinical training requirements that help companies achieve these objectives, companies start with these seven criteria:

1. **Web-Based Technology:** A Software as a Service solution (SaaS) enables simultaneous global distribution, a cost-efficient "pay as you go" pricing model, convenient "anywhere" access for both employees and third parties, and reduced IT investment.
2. **High Security:** The system must include a secure, validated infrastructure that enables electronic communication with study personnel, overcoming the challenge of opening up a sponsor's internal firewall to a myriad of external parties; for data integrity purposes, the system should meet the stringent computer validation requirements of the FDA.
3. **Ability to Host Content:** Rather than have a site manager or clinical researcher review documents that reside on an internal network server, sponsors can store critical protocols, amendments, patient recruitment criteria, conflicts of interest forms and other documents on a secure server, reducing multiple network sign-ins. A secure content hosting option, then, improves the user experience while eliminating the strain on the company's IT support team.
4. **Integrate with Key Applications:** The system must be able to easily integrate with the existing clinical ecosystem, which may include the clinical trial management system, document management system, or EDC, enabling a seamless process that presents a researchers's qualfication on the CTMS directly. With integration, site personnel are automatically added to eClinical training system, and protocol amendments automatically trigger new qualification assignments.

ECLINICAL QUALIFICATION SOLUTION

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5. **"Testing Out" of Training:** The eClinical qualification solution should enable experienced employees and personnel to "test out" of specific training content, especially if training is an annual requirement, such as core GCP principles. For example, UL can build courses that enable site personnel to "test out" of specific topics, based on an automated "pre-test" that covers the entire course.
6. **Deliver Flexible Reporting:** The eClinical qualification solution should help the sponsor company identify the training status of investigators and other site personnel for future recruitment.
7. **Ability to Grant Third-Party Credits:** The eClinical qualification solution should enable site managers to "grant" credit to GCP educational activities taken by site personnel, enabling individuals to upload certificates from GCP education activities they have completed.

TARGETED CLINICAL EDUCATION

It is critical that each investigator and clinical research associate within each study, and in each location, receive just the training that matters to their role within the study.

About UL's eClinical Qualification Solution

Many companies rely on UL's ComplianceWire to manage training for all employees as well as study project managers, research coordinators, monitors and investigators. Our Clinical Libraries cover topics such as the FDA's Bioresearch Monitoring (BIMO) program, Good Guidance Practice (GGP), HIPAA, informed consent and specific roles within a study.

All training is tracked and organized for audit purposes. In addition, the UL Clinical Learning Platform includes assessment tools that enable sponsors to confirm the study personnel's understanding of key study knowledge and obligations.

Under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and technology designed to meet 21 CFR Part 11 requirements for ORA-U, the FDA's virtual university.

FOUR GUIDING RULES FOR EMBEDDING ECLINICAL QUALIFICATION

Once the requirements are satisfied, the next logical step for the organization is to structure the eClinical qualification solution that achieves the stated compliance and business metrics.

As noted earlier in this paper, often these objectives center on meeting regulatory obligations, improving safety, streamlining the approval process, standardizing training qualifications, strengthening site personnel's competencies, and reducing administrative time and effort.

Based on our experience with our own compliance training platform, we recommend the following four rules for building your eClinical qualification framework:

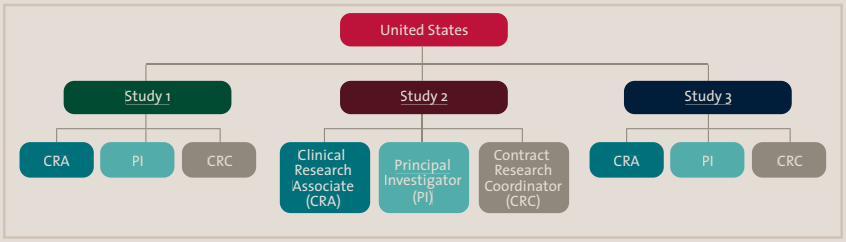
1. **Align Training Requirements with Clinical Roles:** Ensuring training compliance requires accurate, timely distribution of protocols, GCP content and other areas (such as use of Electronic Data Capture applications) to all responsible parties, and consistent naming conventions ensure the administrator has the ability to easily locate the right document for reporting and modification reasons. The eClinical Learning Management System (LMS) should provide these features:
   - Organize each study by geography, sponsor, product, etc.
   - Build User Groups by role or title (PI, CRA, CRC, etc.)
   - Identify qualification criteria and activities that make up the criteria. The chart on the left demonstrates a typical Clinical Training and Reporting Structure. The categories must be segmented into protocol and non-protocol activities (eg GCP requirements) must be organized into curricula.

   For example, the site manager may require courses that highlight the global legal responsibilities of sponsors, monitors and investigators; selection of investigators; investigational site selection; monitoring requirements; and the role and responsibilities of Institutional Review Boards (IRBs).

   Beyond these basics, however, you may require additional courses of study that range from understanding international ethics requirements to international standards of informed consent.

Clinical Education Structure

Category:	Example(s):
GCP Training	US, Europe, Asia
Role-Specific	Primary Investigator Sub-Investigator Monitor Study Coordinator
Study-Specific	Protocol, Reports



In this example, the chart illustrates qualification roles structured first by country, then specific study, then roles within that study. This enables specific content to be distributed once to all individuals according to the organization's particular structure.

2. **Build a Training Hierarchy that Accommodates Growth:** In many cases, the system is expected to grow as the CRO gains additional sponsors and manages trials around the world. It is critical that each investigator and clinical research associate within each study, and in each location, receive just the training that matters to their role.

   For this reason, the eClinical qualification solution must be flexible enough to accommodate your unique training structure. Within ComplianceWire, clients gain several efficiencies of grouping site personnel in this type of hierarchy:

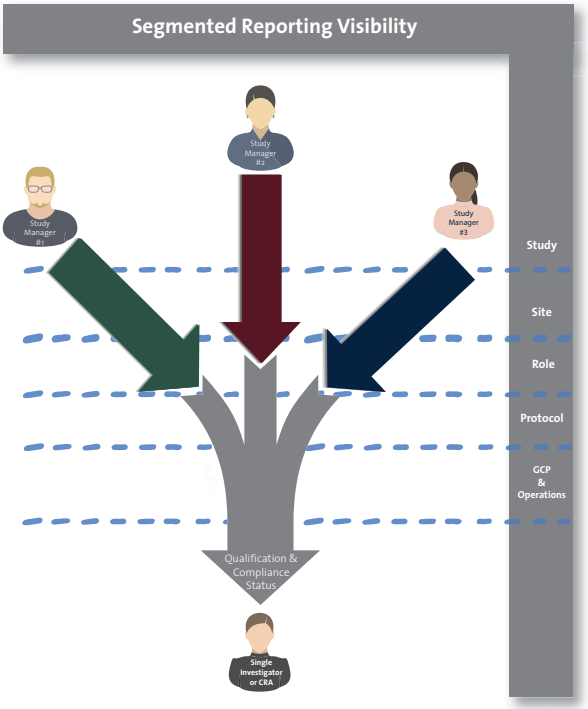
   - Reduction of training content overlap
   - Automatic maintenance of training assignments as new site personnel
     are added to specific user groups
   - Targeted reporting to identify training gaps

   These qualification standards enable consistent and meaningful reporting
   metrics that are measurable at every level of the organization down to a specific role within the study. The roles within each study can be segmented so that the site manager or system adminstrator can easily maintain the content for a particular role within a particular study, and generate qualification reports to identify knowledge gaps.

3. **Develop a Process for Maintaining Site Personnel Data:** To organize site personnel and align them into defined training requirements, the clinical management team must define and maintain meaningful user data attributes. This can be accomplished via manual or automated means. Data integrity and the ability to view real-time information is critical. Common "user" attributes, such as name, e-mail, and organization, can be fed from the CTMS. In addition, the eClinical qualification solution must use four clinical site personnel "attributes": study, site, role and region, to provide segmented visibility to the sponsor's site managers.

4. **Provide Segmented Management Visibility:** The delivery and tracking of qualifications must be segmented, so that study managers can only see what site personnel progress as it relates to the attributes noted above. Ideally, these qualifications should be displayed where site personnel records are stored.

Successful site personnel qualification requires that study, site, role and protocol attributes be attached to each individual in the study - this ensures that each study manager only gains visibility into the specific qualification of that individual.



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.

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