Life & Health

Clinical Communiqué

MARCH 2013

CREATe Clinical Research Courses Now Available in Chinese Mandarin

The "Core Knowledge" courses within the CREATe program [www.dcricreate.com] were recently translated into the Chinese Mandarin language.

This allows clinical researchers enrolled in the CREATe program to select courses in either English or Chinese Mandarin. The CREATe system interface is already available in Chinese Mandarin, providing a truly localized experience for China-based clinical researchers.

continued on page 2

Aboute CREATe

The Clinical Research Education and Training via eLearning program (CREATe) is a partnership with UL providing courses authored by experts at Duke Clinical Research Institute (DCRI). The mission of CREATe is to build a qualified clinical research workforce capable of conducting clinical trials.

The CREATe program consists of DCRI-authored learning assessments and modules designed for the novice investigator and key research personnel seeking a strong foundation for a career in clinical research. Through CREATe, sponsors can enroll selected medical researchers from around the world, and as part of the program, conduct knowledge evaluations to identify knowledge and competency gaps.

Benefits for Clinical Researchers:
Upon completion of the program, clinical researchers receive a portable DCRI certificate of completion that provides them with recognition across multiple participating sponsors.

Benefits for Sponsors and CROs:
Organizations can strengthen relationships with clinical research teams in global regions; they can also use CREATe to measure clinical researchers knowledge through online assessment tools. A baseline evaluation and post-course evaluation provide assurances to sponsors that clinical research teams have acquired the core knowledge they need to conduct safe and successful trials.

Courses currently reflect a U.S. regulatory framework, but can be customized to reflect local cultural values and customs:

- Audits and Inspections: Identifying Fraud and Misconduct
- Drug Safety and Adverse Event Reporting
- Evolution of Clinical Research and Drug Safety
- How is Clinical Research Regulated?
- Human Research Protection Program
- Informed Consent Part I and Part II
- Phases of Clinical Research
- Recruitment, Retention, and Lost to Follow-Up
- Responsibilities of a Clinical Research Coordinator (CRC) in FDA-Regulated Studies
- Responsibilities of Investigators Conducting FDA-Regulated Studies

In addition, a new course is being developed that focuses on China clinical regulations.

STREAMLINING THE CRC EFFORT

Through Essential "eDocumentation"

The clinical research coordinator (CRC) plays an extremely critical role in the clinical trial, acting as a liaison to the investigator, sponsor and monitor.

And with the advent of "eClinical" technology, CRCs are able to reduce the time they spend on distribution and filing of "essential documents." ICH GCP defines essential documents as those documents that "individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of GCP and with all applicable regulatory requirements." (Source: ICH GCP, Section 8.1)

Many sponsors require that essential documents be maintained according to sponsor standards. And traditionally, sponsors have supplied a binder or other receptacle for the hard copy versions of those documents. For the CRC, being able to deliver and receive essential documents more efficiently can result in a more successful trial. What's more, audits generally focus on these documents to confirm that the trial is being conducted properly and that data is accurate.

Today, some sponsors are turning to electronic storage of these documents, which may involve both a Clinical Trial Management System (CTMS) and a training system such as ComplianceWire® to manage "role-based" document delivery.

In fact, ComplianceWire is often used by the clinical management team to deliver and capture receipt of documents with an electronic signature, greatly reducing the effort of the CRC, while also improving accuracy of information. We refer to this as Essential eDocumentation.

Here are some examples of how the following forms and documents have been managed in ComplianceWire:

Form/Document	ComplianceWire Functionality
Form FDA 1572	Forms
Investigator Brochure	CICS (PDF)
Signed Protocol and Amendments	Forms
SOPs	CICS
Informed Consent Form	Forms
Financial Disclosure Form	Forms
Insurance Statement	CICS
Signed Agreements Between Investigator/Institution and Sponsor	Forms (Dual Signature)
Curriculum Vitae	CV Builder (for storing CV s)
Laboratory Manual	CICS (PDF)
Instructions for Handling of Investigational Product	CICS (PDF)
Adverse Event Policy	CICS (PDF)

Obtain Financial Information from Investigators Using Forms

As noted in the last article, the Financial Disclosure form is an essential document, and for good reason. Before permitting a clinical investigator to begin participation in an investigation, the sponsor must obtain accurate financial information. This will enable the sponsor (or applicant) to submit complete and accurate certification or disclosure statements.

The sponsor is also required to obtain the clinical investigator's commitment to promptly update information if any relevant changes occur during the course of the investigation and for one year following completion of the study.

By collecting information prior to study start, the sponsor will be aware of any potential problems, can consult with the agency early on, and take steps to minimize the potential for bias.

For some sponsors and CROs, the effort to capture the Financial Disclosure Acknowledgement policy can be managed in ComplianceWire using UL's Forms tool. Conducting this electronically in ComplianceWire provides three main benefits:

1. Sending the policy in electronic format makes it easy for most investigators to review and respond to questions; answers can be immediately routed electronically to the compliance team.
2. Investigators can "electronically sign" the policy, and return to view policy and responses at any point in the future.
3. The record is saved along with the investigator's transcript of other acknowledgement and training records for streamlined audit preparation.

How FDA Evaluates Financial Information Disclosed by Investigators

FDA will evaluate disclosed information for each covered clinical study in an application to determine the impact on the reliability of the study's data. FDA may consider the size and nature of a disclosed financial interest (including the potential increase in the value of the interest if the product is approved) and steps that have been taken to minimize the potential for bias.

Applicants also need to provide information on clinical investigators who participate in foreign studies, and should include either a certification or disclosure of information for clinical investigators participating in foreign covered studies. If the applicant is

continued on page 5

unable to obtain the information despite acting with due diligence, the applicant can submit a statement documenting his or her efforts to obtain the information. In this case, it is unnecessary to submit a certification or disclosure form.

If FDA determines that financial interests raise serious questions about the integrity of data, for example, the agency will take any action it deems necessary to ensure the reliability of the data. FDA may initiate agency audits of data from the clinical investigator in question; request that the applicant submit further analyses, or request that the applicant conduct additional independent studies to confirm the study results. FDA may also refuse to acknowledge the covered clinical study as having provided sufficient data for agency action. In some cases, refusal to file financial disclosure information can lead to FDA's refusal to file a New Drug Application (NDA).

You can learn more through our online course, Financial Disclosure by Clinical Investigators (Code: GCP24), which summaries the 21 CFR Part 54 (Financial Disclosure by Clinical Investigators). The course explains in detail which financial arrangements must be disclosed, as well as investigator and sponsor responsibilities when disclosing financial information.

Meet UL Representatives at the Proactive GCP Compliance Event

Join UL at the Fourth Annual Proactive GCP Compliance Conference being held on April 10th through 12th in Washington, DC. **View the agenda** [www.exlpharma.com/event-agenda/3320]. The UL table will be just outside the conference rooms.

If you are attending, please stop by for a demonstration of the **CREATe program** [www.dcricreate.com] as well as our other **clinical training solutions** [www.uleduneering.com/industries/medical-device/clinical-trials/].

When you register, please use the code C262UL TO RECEIVE A 15% DISCOUNT off the standard registration fee, as a special thank you from UL.

The event features panel discussions on these topics:

- **Technology:** How has Technology Changed the GCP Process?
- **Risk-Based Monitoring:** How Different Companies are Developing and Executing an Effective Risk-Based Approach to Clinical Monitoring and the Impact on Clinical Processes, Quality and Cost
- **Measuring Clinical Quality:** Experts Share Specific Strategies for Identifying, Tracking and Interpreting Key Quality Indicators, Key Performance Indicators and Key Risk Indicators
- **Internal Operations:** How Varying Companys' Internal Responsibilities are Divided and Shared among Quality, Compliance and Clinical Teams
- **Inspection Readiness:** Experts with Inspection Experience Share Lessons Learned and Proactive Strategies for Ensuring Inspection Readiness on a Global Scale

About UL

UL is a premier global independent safety science company. UL develops technology-enabled knowledge solutions for helping to assure regulatory compliance and improve business performance. For more than 30 years, the company has served corporate and government clients in the Life Science, Health Care, Energy and Industrial sectors using our award-winning learning management platforms, unique regulatory and business content and professional services.