



Tulsa Chapter Meeting
December 13, 2011

Webinar

September 2011 FDA Safety Reporting Requirements for Clinical Trials: Tips for Compliance

When: Tuesday, December 13, 2011
11:00 am-12:30 pm Webinar and Lunch
12:30 pm-12:45 pm Business meeting, door prize drawing

Where: OU-Tulsa Campus
Learning Center Room 145
4502 E. 41st St.
Tulsa, Oklahoma 74135

Costs: Lunch will be provided. If you wish to receive 1.5 contact hours, it will be \$10 for ACRP members and \$25 for non-members payable online at the ACRP website.

Please RSVP to JJ Hale: jj.hale@ctca-hope.com no later than Friday, December 9 by 5 pm. For questions, please call Kathy Buchanan at (918) 744-2453 (office) or (918) 740-4045 (cell).

Objective of this Webinar

Adequate monitoring and reporting of adverse events in a clinical trial is one of the most important elements of Good Clinical Practices, and required by law. To address the common misunderstandings of safety reporting requirements, FDA announced several major revisions in the IND safety reporting regulations. **These new requirements became effective on September 28, 2011.** Noncompliance could lead to regulatory actions by the FDA.

Major changes introduced by these new rules are requirements for investigators to:

- Assess relationship and causality of adverse events
- Define criteria for expedited reporting to FDA and IRBs
- Analysis of all adverse events
- Increase role of sponsor

These new requirements also apply to the bioavailability and bioequivalence (BA/BE) studies (studies for generic drugs).

Sponsors, investigators, IRBs, and other personnel responsible for reporting safety related information from clinical trials with a new investigational product or a generic drug must educate, implement, and prepare for FDA inspections for compliance with the new rules.

Areas to be covered in the training:

- Current regulatory requirements
- Rationale for these changes
- Role of clinical investigators and sponsors
- Amending existing SOPs and/or creating new ones
- Training requirements for personnel,
- Good documentation practices for safety monitoring

The presentation of this webinar will include slides, polling questions, handouts, case studies, and audience Q&A.

What You Will Learn

Upon completion of this webinar, attendees should be able to:

- List key additional obligations in the new rules and be able to understand the rationale behind the changes in requirements.
- Revise safety reporting procedures to address classification of adverse event, expanded role of investigators and sponsors, and time-lines for reporting to IRB and FDA.
- Define new training requirements for all personnel, understand key FDA concerns and prepare for FDA queries and audits.

Who Will Benefit From This Webinar

This activity is intended for CRAs, CRCs, Clinical Research Administrators, Medical Writers, Pharmaceutical Physicians, Pharmacovigilance Monitors, Principal Investigators, Project Directors, Project Managers, and Regulatory Affairs Associates & other staff.

Meet Your Presenter

Mukesh Kumar, PhD, RAC leads the Regulatory Affairs and Quality Assurance departments at Amarex, a full service regulatory affairs and clinical trials company based in Germantown, MD. He is an expert in global regulatory affairs, clinical trials and multi-national project management for drugs, biologics and medical devices. He has been involved in about 100 clinical trials in more than 40 countries, has made several hundred submissions US FDA, EMA and regulators in several other countries. He has authored numerous articles in peer-reviewed journals and given presentations for several professional and academic organizations worldwide.

Disclosure Statement

Dr. Mukesh Kumar states that he has no actual or potential financial conflict of interest in relation to this program.

Program Numbers

Association of Clinical Research Professionals



The Association of Clinical Research Professionals (ACRP) provides 1.5 contact hours for the completion of this educational activity with the completion of the online evaluation form. These credits can be used to meet the certification maintenance requirement (Program Number ACRP-2011-WEB-325).

Continuing Nursing Education



The California Board of Registered Nursing approves the Association of Clinical Research Professionals (ACRP) as a provider of continuing nursing education. ACRP's webinar program provides 1.5 contact hours of continuing nursing education credit (Program Number 11147-2011-WEB-325).