



Red River Valley Chapter

Presents

Staying Ahead of the Curve: Avoid Being Caught Off-Guard by GCP Audits

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Wednesday, March 23rd 11:00 am – 12:30 pm

Cetero Research, 4801 Amber Valley Parkway, Fargo, ND

Brief Program Description: Compliance is essential to ensure that the rights, safety and well-being of trial subjects are protected and that the clinical trial data are credible. Early detection and management of any clinical study issues can help you ensure that a clinical trial will be compliant with regulatory requirements and applicable guidelines. There are activities that may help you prepare your organization and your site for the audit.

This presentation will help you, through case studies, to become more familiar with the audit process and will broaden your competence in identifying on a day to day basis, pitfalls and discrepancies that can occur during clinical trials. This course will also give you pointers on how to manage problems identified during the course of any clinical trial. Case studies in combination with polling questions will be used to identify the appropriate CAPA for each case study. Finally, this course will in turn provide you with tools that can improve compliance in your daily operations.

Program Objectives:

- 1 Identify preventing issues that will help ensure continuous compliance during a clinical trial.
- 2 Identify common findings of GCP audits and provide tips on how to prepare for an audit.
- 3 Identify corrective actions and describe tools to improve compliance.

Program Agenda: Sign-in begins at 10:45 am, Webinar viewing from 11:00 am until 12:30 pm, Q and A to follow.

Target Audience: This webinar is intended for Clinical Research Associates (CRAs), Senior CRAs, Clinical Research Coordinators (CRCs), Clinical Research Administrators, Principal Investigators, Project Directors, and Project Managers.

Registration Information: Register on-line by 03-23-11 at www.acrpnet.org (follow the Chapter link)

Cost: Chapter Member viewing – Free	Chapter Member CEUs - \$10
Non-Chapter Member viewing - \$10	Non-Chapter Member CEUs - \$10 (in addition to viewing fee)
Non-ACRP Member viewing - \$10	Non-ACRP Member CEUs - \$25 (in addition to viewing fee)

Payments will be made on-line (credit or debit card). For information regarding cancellation and refund policies, please refer to www.acrpnet.org.

Contact hour(s): Contact hours (1.5) have been applied for through ACRP. In order to receive contact hours, you will be responsible to complete the evaluation form. This form will be posted directly to your record on the ACRP website 10 days following the event and will be available to complete for 30 days.