

2009 Web Seminar Series

## Quality Assurance and Site Monitoring Visits

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## Introduction

- This is a one-hour seminar providing guidance to CTN clinical research sites on quality assurance monitoring preparation, facilitation, and follow up procedures.
- Participants will receive an all-encompassing clarification of monitoring expectations.

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## Training Outline

- Topic 1: Types of CTN site monitoring visits
- Topic 2: Preparation
- Topic 3: Monitoring visit expectations
- Topic 4: Post visit responsibilities
- Topic 5: Quality control processes between visits

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Polling Question



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### Terminology

- Quality Assurance - All those planned and systematic actions established to ensure the trial is performed and the data are generated, documented (recorded), and reported in compliance with GCP and the applicable regulatory requirement(s).
- Quality Control - The operational techniques and activities undertaken within the quality assurance system to verify the requirements for quality of the trial-related activities have been fulfilled.

Source: Good Clinical Practice: A Question & Answer Reference Guide (May 2006)

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### ICH & CFR Monitoring Requirements

- ICH E6 Section
  - 5.18.1: Purpose of monitoring
  - 5.18.3: Extent and nature of monitoring
  - 5.18.4: Monitor's Responsibilities
  - 5.18.6: Monitoring reports
- 21 CFR 312 Subpart D: Sponsor's responsibilities

6

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## Types of CTN Site Monitoring Visits

- CCC
  - Initiation
  - Interim (routine)
  - Close-out
  - For Cause
- Node
  - Initiation
  - Interim (routine)
  - Close-out
  - For Cause

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## Preparing for Site Monitoring Visits

- Review performance metrics
  - Node & CCC monitoring templates - in handouts
- Sign and return the site visit confirmation memo
- Arrange space and internet access for monitor
- Avoid conflicts of interest
- Make binders accessible
  - Participant
  - Regulatory

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## Preparing for Site Monitoring Visits

*Continued*

- Coordinate
  - Pharmacy audit
  - Facility tour
  - Meeting with Principal Investigator
- Resolve outstanding action items
- Understand your study role and responsibility
- Consider staffing adjustments for the visit date

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What preparation tasks have you found helpful?

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### What to Expect During a Site Monitoring Visit

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- Visit in general
  - Works Independently
    - study material review
  - Periodic questions or discussions as needed




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### What to Expect During a Site Monitoring Visit

*Continued*

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- Have monitor sign site visitor log
- Prepare for brief planning meeting with monitor
  - Schedule for the day
  - How issues will be flagged
  - What binders will be reviewed
  - Visit wrap-up/summary meeting time
- Monitor will potentially review any study materials
- Ensure availability for inquiries or requests from the monitor

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### **Site Responsibilities: Post Monitoring Visit**

- Careful QA report review
- Appropriate resolution for action items
  - Resolve discrepancies
    - queries and data
    - drug accountability
  - Report protocol violations
  - AE/SAE follow up reporting
  - Submit any outstanding regulatory documentation
  - Address consent issues

13

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### **Quality Control Processes Between Visits**

- Ongoing study chart review
  - Team approach
- Retrospective resolutions – costly
- Apply lessons learned proactively
  - Avoiding repeat errors
- Ensure training for new hires
  - Include monitor visit expectations

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What steps do you take between visits to assure your quality control processes?

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Polling Questions



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**Resources**

- Handouts
  - Blank monitoring report templates
    - CCC
    - Node
  - Guidance for Industry E6 Good Clinical Practice
  - Monitoring Clinical Investigations Guidance
  - Preparing for Clinical monitoring visits and FDA Audits
- GCP question and answer reference guide (updated yearly) by Barnett \$45.95
  - Regulatory issues
  - Consent issues
  - Glossary of terms

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**Summary of Training**

- Types of CTN site monitoring visits
- Preparation
- Monitoring visit breakdown
- Post visit responsibilities
- Quality control recommendations

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A copy of this presentation will be available  
electronically after the meeting from:

CTN Dissemination Library

<http://ctndisseminationlibrary.org>

and

NIDA Livelink

<https://livelink.nida.nih.gov>

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