Advantage Clinical

# Inspection / Audit Preparation

## Clinical Research Sites

Clinical trial sites and investigators are routinely audited & inspected by their trial Sponsors, CROs, ethics boards and most dauntingly local regulatory authorities (Food and Drug Administration (FDA), Health Canada etc).

The findings uncovered in these audits may have cascading consequences for unprepared sites and investigators. They may lead to the suspension of a trial at a site or even cessation of all research related activities until the findings have been resolved.

This short course has been designed to help clinical trial sites prepare for the possibility of a routine, or for-cause audit. The information presented in the course outlines the common rational for audit targeting, preparing your site for an audit, hosting the audit through to responding to audit findings and implementing corrective and preventative action.

Contributing authors to this course include:

- Lead Canadian / US Good Clinical Practice auditor
- Sponsor Quality Assurance and Clinical Operations Personnel
- Site Clinical Research Coordinators who have undergone Sponsor, IRB and FDA audits

### Module Content Breakdown

1. Audits vs ongoing monitoring
    a. Auditing
    b. Monitoring
    c. Quality Assurance
    d. Quality Control
2. Who can audit your site?
    a. Sponsors and CROs
    b. Ethics Boards
    c. Regulatory Authorities
3. Audit Target Considerations
    a. What factors are considered by auditors when selecting sites to audit

4. Preparing for an audit
    a. What to do after you have been selected for an audit
    b. Preparing for the auditor's arrival
    c. Documents and Processes to review
        i. What to look for when reviewing
    d. How and when to make corrections and notes to file (memos)
    e. When to avoid correcting documents and processes
    f. What documents to have ready for review
    g. What documents can and cannot be viewed by the auditor
    h. Enlisting your Sponsor/CRO/IRB to assist in audit prep
5. During the audit
    a. What to do when auditors arrive
    b. How to respond to auditor interviews
    c. Requesting and responding to daily and audit de-breifs
6. Follow up and consequences
    a. Responding to audit findings
    b. Opening a Corrective Action Preventative Action Plan (CAPA)
    c. Conducting Root Cause analysis
    d. CAPA and Root Cause Case Study
7. Top 8 Common Audit findings

For more information on the Inspection / Audit Preparation course and more course offerings please visit www.Advantage-Clinical.com or contact us at:

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