ICH GCP E6 R2
Meeting CRO-Vendor Oversight Requirements

An Interactive Workshop Presented by FDAnews and Wool Consulting Group
March 27-28, 2019 • Marriott Raleigh Crabtree Valley • Raleigh, NC

Agenda

Day 1

8:00 a.m. – 8:30 a.m. **Registration/Continental breakfast**

8:30 a.m. – 10:00 a.m.

- **Welcome and introductions**
- **Review learning objectives**
  - **Interactivity:** What do you want to learn in this course?
  - Discuss the course pre-reading materials
- **Foundational terminology review and regulatory authority communications regarding CRO-Vendor Oversight**
  - ICH GCP E6 R2 5.2.1-5.2.3 review
  - Definitions: CRO and Vendor
  - FDA communications
  - MHRA communications
  - EMA communications
  - **Discussion:** Attendee experiences with regulatory inspections – for CRO/Vendor oversight

10:00 a.m. – 10:15 a.m. **Break**

10:15 a.m. – 12:00 p.m.

- **What CRO and Vendor activities require 'oversight'**
  - **Interactivity**: Self-assessment of the CRO-services and Vendors used in the attendees' organizations
  - **Interactivity**: Vendors used in clinical trials and CRO services typically used in the conduct of clinical trials
  - **Interactivity**: Determine Vendors and CRO services that directs sponsor oversight
  - CRO services requiring oversight
  - Vendors requiring oversight

12:00 p.m. – 1:00 p.m. **Lunch**

1:00 p.m. – 2:30 p.m.

- **Foundational Framework to Implement CRO-Vendor Oversight**
    - Mapping the CRO services and Vendors used for a trial to determine oversight methods and approaches
    - CRO-Vendor Oversight Framework
    - CRO-Vendor Governance
    - Access to CRO-Vendor SOPs and policies, etc., to perform oversight
    - **Discussion**: Right – fitting the governance for your organization

2:30 p.m. – 2:45 p.m. **Break**

2:45 p.m. – 4:30 p.m.

- **Processes and Procedures for Effective Implementation**
    - Policies, Processes, Procedures (SOPs), templates
    - Governance structure and documentation
    - Helpful tips for implementation
    - **Interactivity**: Implementation challenges attendees are encountering currently and class discussion to identify possible solutions

<u>Day 2</u>

8:00 a.m. – 8:30 a.m. **Continental breakfast**

8:30 a.m. – 10:00 a.m.

- **Review and re-cap of Day 1**
- **Effective and Compliant Oversight Methods**
    - **Interactivity**: How would you respond to the following question during a regulatory authority inspection – "how did you manage your trial for quality?"
    - Begins with 'defining' 'quality work products' to be delivered by the CRO/Vendor
    - Critical to success communication pathways
    - Partnering with Clinical Quality Assurance
    - **Interactivity**: How does industry/your organization perform CRO-Vendor oversight?
    - Oversight goes beyond the 'Transfer of Obligations Matrix'
    - Detailed review of various activities employed in industry that meet 'oversight methods'
    - Identification, approval and oversight of CRO/Vendor sub-contractors

10:00 a.m. – 10:15 a.m. **Break**

10:15 a.m. – 12:00 p.m.

- **CRO-Vendor Oversight Plans**
  - Organization is in a state of 'control' and 'oversight' of the trial and CRO-Vendors supporting the clinical trial
    - Plan
    - Do
    - Check
    - Act
  - **Interactivity**: Identify elements of a CRO-Vendor Oversight Plan
  - Review key elements of a CRO-Vendor Oversight Plan for development of an organizational template
  - eTMF/TMF documentation of Sponsor oversight and Vendor oversight of their sub-contractors

12:00 p.m. – 1:00 p.m. **Lunch**

1:00 p.m. – 2:30 p.m.

- **Common Pitfalls to Effective Implementation and Approaches to Mitigate the Pitfalls**
  - Internal assessment of the clinical trial outsourcing model (sponsor delegated duties, functions, and activities, activities performed in collaboration with the sponsor or another Vendor in the trial, duties, functions and activities the sponsor retains for the trial)
  - **Interactivity**: Self – assessment of duties, functions and activities the sponsor organization retains responsibility for - for the trial, or a CRO/Vendor who is sub-contracting to another party
  - Internal assessment of capabilities to perform oversight
    - Budget
    - Planning
    - Resources
    - Equipping staff
    - Time
    - Processes for work product assessments, documentation, feedback and follow-up of the oversight performed
    - Documentation
    - Continuous improvement
  - **Interactivity**: Lessons learned with a CRO or a Vendor and the process improvements you put in place
  - Assessing adherence to SOPs, processes, plans and governance structure – actions and documentation!
  - Assessing effectiveness of the oversight methods employed – actions and documentation!
  - **Interactivity**: Solutions-approaches to mitigate the pitfalls presented and discussed
  - **Discussion**: Does the lack of funds, people and time impact the organizations requirement to perform oversight of the CRO-Vendor performance on the clinical trial? What do the regulatory authorities say about oversight in resource, budget-constrained organizations?

2:30 p.m. – 2:45 p.m. **Break**

2:45 p.m. – 4:30 p.m.

- **Regulatory Authority Inspections: CRO-Vendor Partnership and Oversight**
  - Review anecdotal reports of key regulatory authority inspections for CRO/Vendor Oversight
  - FDA
  - EMA
  - MHRA
  - **Discussion**: Inspection readiness – 'when does this occur?'
- **Wrap-up**
  - Review of workshop learning objectives
  - Review of attendee learning needs shared on Day!

4:30 p.m. **Workshop Adjourn**