What is ICH E6(R2)?

ICH E6(R2) is an addendum to the International Council for Harmonisation E6(R1) that provides Good Clinical Practice (GCP) guidance and "a unified standard for the European Union, Japan, and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in those jurisdictions."[1]

The guidance was updated in March 2018 and one section outlines sponsors' oversight responsibilities when clinical studies are outsourced to contract research organizations (CROs). Section 5.2.1 of the guidance states "A sponsor may transfer any or all of the sponsor's trial-related duties and functions to a CRO, but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor."

Regulatory bodies can issue major or critical findings for non-compliance, so study oversight is critical for outsourced clinical trials.

KEY TAKEAWAY: Sponsors have a regulatory responsibility to ensure trial quality, integrity, patient safety, and internal sponsor and partner adherence to standard operating procedures (SOPs).

How Can Sponsors Ensure Continued Oversight?

Sponsors must be able to demonstrate to inspectors they maintained oversight throughout the course of the study. Here are several examples of documentation and evidence sponsors should be able to provide for oversight:

- Trial status meeting minutes
- Site communication logs
- Record of action items and follow-up tasks
- CRO audit results
- Performance metrics and reports
- Reviews and approvals for monitoring visit reports
- Issue escalation procedures
- Records of protocol deviations and resolutions

In addition, roles and responsibilities should be documented in contracts to ensure clear delegation of trial activities.

OVERSIGHT

- **Ensure the safety of study subjects in an outsourced environment**
- **Measure and control the performance, deliverables, and efficiency of CROs carrying out outsourced tasks on behalf of the sponsor**

KEY TAKEAWAY: **Sponsors should clearly define their oversight strategy and retain documentation and evidence as proof for inspectors to avoid compliance findings.**

Learn how Vault CTMS enables effective study and CRO oversight in one cloud system.

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[1] Guideline for good clinical practice E6(R2). European Medicines Agency.