R&D and Clinical Trials Compliance Update

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Session Agenda

- Enforcement update
- Best practices for developing and implementing an effective clinical compliance program
- Emerging trends

Areas of R&D and Clinical Trial Enforcement Risk

Risk Area	R&D Activity	Potential Consequences
AKS / FCPA	• Engagement of KOLs / HCPs as consultants • Interactions with governments in high risk countries • Recruitment / compensation of investigators • Post-marketing, retrospective studies, or IITs • Use of CROs and other third parties	• Criminal enforcement • SEC enforcement • False Claims Act case
FDA / GCP / GxP	• CRO selection, trial design, and oversight • Data integrity and data management • Clinical product and supply chain • Submissions to FDA and ex-U.S. agencies	• "Fraud on FDA" False Claims Act case • FDA Warning Letters • CRLs / application failure
Clinical Trial Fraud	• Investigation site oversight • Trial protocol deviations • CRO / third party engagement	• Wire Fraud • Other criminal fraud enforcement • CRLs / application failure

AMB Research Center, Inc. – September 2023

- Defendants: Miguel Montalvo Villa (AMB President) and Ivette Portela Martinez (clinical trial site pharmacist)
- Conviction at Trial: September 7, 2023 (Miami, FL)
- Offenses: Wire Fraud; Conspiracy To Commit Wire Fraud
- Key Allegations:
  - Falsification of trial participants – subjects were included without their knowledge in clinical trial documents and databases
  - False statements to FDA during 2018 inspection re: informed consents
  - Submission of false and fraudulent invoices for clinical trial work

> "Reliable and accurate data from clinical trials is the cornerstone of FDA's drug approval process. The jury's finding demonstrates that those who attempt to subvert the regulatory functions of the FDA by making false statements to the agency will be held accountable for their actions," said Special Agent in Charge Justin C. Fielder of the FDA Office of Criminal Investigations Miami Field Office. "We commend the efforts of the Department of Justice for vigorously pursuing the prosecution of this matter."
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> - DOJ Press Release, September 7, 2023

R&D Compliance Program Design and Best Practices

Stages of the Clinical Trial Process

Each stage presents risk + opportunity for oversight / mitigation

Case Study

- You work as Head of R&D Compliance at a mid-sized pharma company with one drug on the market for a rare disease indication and a robust pipeline
- The VP of R&D at your company comes to you about initiating a clinical trial for a promising COVID treatment and provides the following information:
  - Trial design is a Phase III trial with 200 patients and investigation sites in the United States, Germany, and India
  - Process is under way to qualify a global CRO, who will then subcontract with a local CRO in India
  - Plan is to conduct remote monitoring of sites and patients to record changes to patient symptoms
- **What steps should you take to mitigate compliance risk?**