



Life Sciences Corruption Risk: Clinical Trials and Other Areas

International Pharmaceutical Regulatory and
Compliance Congress and Best Practices Forum

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Background

- ▶ Traditional pharma corruption efforts focus on “health care” compliance
 - ▶ Detailing to health care providers (HCPs)
 - ▶ Speaker programs
 - ▶ Medical education
 - ▶ Research grants
 - ▶ Sponsorships
 - ▶ Donations
- ▶ Policies and compliance programs must cover all areas of the business where interactions with government officials occur

Additional business areas

- ▶ Clinical trials
- ▶ Regulatory
- ▶ Manufacturing
- ▶ Human resources
- ▶ Customs and duties
- ▶ Local licenses and permits

Clinical Trials

- ▶ Third party issues for investigators, CROs
 - ▶ Due diligence
 - ▶ Subcontracting
 - ▶ Ownership
 - ▶ Training
 - ▶ Compensation structure
 - ▶ Reps and warranties
 - ▶ Audit rights
- ▶ FDA/SEC referral program for statements that may be false or misleading
- ▶ Interactions with IRBs
- ▶ FDA rules for investigator payments extend to spouse and dependents of the investigator

Understand the Trial

- ▶ Is it necessary?
- ▶ CRO
 - ▶ Selection
 - ▶ Role
 - ▶ Compensation method
 - ▶ Potential interaction with government regulators
- ▶ Investigators
 - ▶ Sufficiency of protocol to support payments?
 - ▶ Determination and documentation of FMV
 - ▶ Number of investigators required
 - ▶ Selection of investigators
 - ▶ Specific duties of investigators and related documentation

CRO and Investigator Payment Considerations

- ▶ Milestone payments
- ▶ Direct payment of travel and lodging expenses
- ▶ Documentation/receipts for other reimbursed expenses
- ▶ Pre-approval of other expenses (e.g. consultants)
- ▶ Limit cash advances to CRO
- ▶ Payments to investigators v. institutions
- ▶ No success fees

Other Interactions with Government Officials

- ▶ Regulatory filings
 - ▶ Drug approval process
 - ▶ Patent and licensing processes
- ▶ Assessment of customs and duties on products
- ▶ Manufacturing
 - ▶ GMP inspections
 - ▶ Environmental inspections
 - ▶ Worker safety inspections
- ▶ Human resources
 - ▶ Immigration
 - ▶ Labor regulators
- ▶ Local business and operating licenses

Managing Corruption Risks for Other Interactions

- ▶ Tone at the top
- ▶ Identify interactions with government officials
- ▶ Understand local corruption laws
- ▶ Create meaningful corruption policies and training
- ▶ Ensure all employees with potential government interaction are trained on corruption policies
- ▶ Assess understanding of the policies and test compliance
- ▶ Track and monitor use of third parties
- ▶ Encourage reporting of potential violations through whistleblower hotlines
- ▶ Discipline violations of compliance policies

Questions?

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