



Clinical Trial Auditing and Data Integrity Concerns and Suggestions for FDA's Consideration

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and Approaches to Good Clinical Practice

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The Weinberg Group: Resolving FDA Issues For 29 Years

- Recognized as leading consulting firm in advisory and compliance markets
- Engaged in all issues facing healthcare firms (e.g., submissions, strategy, Warning Letter response, compliance)
- Leading independent auditor of clinical trials

Two Points Must Be Addressed

- Systematic audits of all clinical trial types should be mandatory
- Audits should be conducted with independence from trial manager

Majority of Audits Outsourced

- Physician retention and study monitoring routinely done outside of sponsor
- Some sponsors audit, some do not
- Most audits led by CRO conducting the trial

Economy and Health Care Rule American Mindsets

- Study after study demonstrates that people care most about the economy and their health
- Regulations exist that require mandatory audits of all public company financial data
- **BUT** no similar requirement exists for healthcare products

Financial Audit Requirement Obvious

- Government oversight of public companies demands full accountability
- SEC regulations govern the process
- Why isn't the same logic that is applied to critical data necessary for product approval?

Integrity of Healthcare Data Equally Important

- Shouldn't the data which governs our health and the products we use be subject to the same level of scrutiny?
- Yet ICH 5.19 only suggests what to do if a sponsor chooses to audit – **and the CFR is silent!**

Audit Independence Also Ignored

- Congress decided financial audits must be independent (Sarbanes-Oxley, section 201)
- Most audits done by CRO conducting trial
- The conflict is obvious – potential exists for disaster – and ignored

Demand Transparency

- Audits should be conducted free from conflict
- Auditors should be chosen by sponsor, not CRO
- CRO should be prohibited from auditing data derived from trials they conduct

Require Audits and Independence

- Add regulations to CFR
- Follow protocol established by financial professionals
- Demand independence in auditors
- Create conflict free, trusted data