Auditing Clinical Data

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Assessing Data Quality and Integrity

- Evaluation of the agreement of data found in source documents with that on CRFs and in regulatory submissions
- Determination of adherence with the study protocol
- Determination of conformity with human subject protections
FDA Record Requirements

- CI retains all relevant information regarding the study as conducted at his/her site – paper and electronic
- Records be complete, accurate, and current
- Records be retained for at least the minimal timeframe indicated in pertinent regulation

Elements of Quality Data

- Accurate
- Legible
- Complete and contemporaneous (recorded at time activity occurred)
- Original
- Attributable (to person who generated data)
Data Integrity

- Credible
- Internally Consistent
- Independently verifiable (Corroborated)

The Data Audit -1-

- Critical Points
  - Did subjects exist; did they show up for study visits as reported?
  - Did subjects meet inclusion/exclusion criteria?
  - Did subjects receive the test article per protocol (frequency and dose)?
  - Is all significant safety/efficacy data corroborated in source data/documents and completely and accurately reported per protocol?
The Data Audit -2-

- Are all source documents available?
- Are data corrections properly made? – original information visible, “corrector” properly identified, rationale included?
- Do results appear too good?
- Are data repeated identically in one or more files?

The Data Audit -3-

- Are entries out of chronological order or data squeezed between the lines?
- Do laboratory reports, consultations, charts, ECGs, or other test results appear to be photocopies?
- Do any signatures on informed consent documents appear similar to one another?
- Does any other required signature appear not to match that of the person identified?
Be On the Lookout

- Shadow Charts
  - What is really the source data here?
- Pre-Signed data sheets or CRFs
- Inconsistencies
- Anything suspicious
Disclaimer:

The information within this presentation is based on the presenter's expertise and experience, and represents the views of the presenter for the purposes of a training workshop.

What This Lecture will Address/Review

- Key Activities in a Clinical Trial
  - The Process Approach
- Brief History of GCP (U.S. and international)
- Goals and Principles of GCP
- Roles and Responsibilities Under GCP
  - Investigators
  - Sponsors/Contract Research Organizations
  - Ethics Committees