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TRIALS

POSTER PRESENTATION Open Access

Investigating possible fraudulent activity at a research site

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Background

A risk-based approach to monitoring clinical trials aims to detect non-compliance with the protocol or regulatory requirements that may compromise the participants' well-being or the trial's ability to produce reliable results.

Method

We describe a pragmatic framework for investigating and evaluating suspicions of poor performance/practice and the steps to be taken if findings suggest fraudulent activity.

Prior to site audit:

- Check reliability of information that prompted concerns
- Prepare dossier of site information, detailing suspect data points
- Arrange visit promptly (but without indicating concerns)

During audit:

- Two auditors: one to ask open questions, the other as witness and scribe.
- Interview staff individually, establishing their knowledge of trial procedures and incident. Note conflicting information.
- Establish key facts:
  1. Were participants real and eligible?
  2. Did they consent?
  3. Are test/clinical measurements/data valid?
  4. Was appropriate treatment/intervention given?
  5. Was follow-up provided, were events reported?
  6. Are participants safe and data reliable?
- Obtain documentary evidence, maintaining confidentiality of trial participants
- Document findings

After audit:

- Implement corrective actions to:
  1. Ensure safety of participants
  2. Address important deficiencies in data quality
  3. Support site: training, additional monitoring/support, replace staff.
- Look for systemic trial quality issues e.g. other staff, other data
  1. Apply lessons/corrective actions to the whole trial
- Notify appropriate parties: Sponsor, steering committee, data monitoring committee, regulatory body, ethics board, host institution, funder, and professional bodies.

Conclusion

Cases of serious misconduct or fraud do occur. Taking a systematic approach to an investigation ensures appropriate action is taken to preserve study intergrity.

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