Questionable Data Arising in Multi-Center Clinical Trials

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Topics for Discussion

I. Define Types of Questionable Data
II. How to Detect It
III. Options for Handling
IV. How to Prevent/Minimize Occurrence

Define Types of Questionable Data

- Fraudulent
  - By Investigator/sponsor
    - Data manipulation
    - Patient manipulation
  - By Patient
    - Misrepresentation of severity or identity
    - Participation in simultaneous trials
    - Intentional non-compliance

Define Types of Questionable Data

- Questionable
  - Due to Sloppiness, Carelessness
    - Ratings and eligibility
  - Due to Short-cutting
  - Due to Staff turnover
  - Due to Distortion of ratings (conscious or unconscious
  - Selective reporting

How to Detect Questionable Data

- Whistle-blowers
- Monitoring by:
    - In-person Data/Coordinating Center
    - DSMB
    - Centralized quality control reviewers
    - Statistical methods

Options for Handling Questionable Data

- Do nothing (preserve principle of ITT)
- Data removal: Invalidate entire study vs Disqualify full site vs Remove only specific data
- Evaluate impact of data removal on results

  conduct sensitivity analyses
- Retain data if it can be rectified/fixed
- Administrative Actions (reporting deviation or misconduct)

How to Prevent/Minimize Occurrence of Questionable Data

- Ethics training on misconduct and reporting
- Staff training on study procedures
- Monitoring (plan and fund)
- Review (early and ongoing)
- Centralized ratings and laboratory assessments
- Data field evaluation and cross-checking
- Reliability Assessment
- Promoting “ownership” of study
- Continuous dialogue with sites in decision-making, etc.