Guidance for Industry. Oversight of clinical Investigations - A Risk-Based Approach to Monitoring (FDA)

http://www.fda.gov/downloads/Drugs/.../Guidances/UCM269919.pdf

SPONSOR RESPONCIBILITIES

- Monitoring contains
  - Identifying critical data
  - Risk assessment
    - Risk should be
      - Identified
      - Analyzed
      - Modified
  - Designing monitoring plan
  - Documenting monitoring activities
- Additional Strategies include
  - Designing protocol and CRF
  - Clinical investigator training and communication
  - Delegation of the monitoring responsibility to a CRO
  - Initiating a site

MONITORING PLAN

- Tailored to a specific Clinical Investigation (CI)
- Includes mix of centralized and on site practices
- Possible components
  - Ensuring quality monitoring
  - Description of monitoring approaches
  - Communication of monitoring results
  - Monitoring plan amendments
  - Management of noncompliance
- Factors to be considered
  - Complexity of the study design
  - Types of the study endpoints
  - Clinical complexity of the study population
  - Geography
  - Relative experience of the CI and the sponsor
  - Electronic data capture
  - Relative safety of the product
  - Stage of the study
  - Quantity of data

MONITORING METHOD

- Centralized
  - Identifies more than 90% on site findings
  - Better detects data abnormalities
  - Prioritizes on site visits
  - Timely identifies higher risk sites
  - Supplements or reduces on site visits
  - Available due to technological capabilities
- On site
  - Needed more intensively in CI with no prior experience
  - Helpful early in the study

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