Roche

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Industry Sponsored or Supported Clinical Trials

Monitoring Considerations

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Outline of Presentation

- Complexity of Industry Clinical Trial Environment
- Monitoring Objectives
- Monitoring Policy and Procedures
- Challenges
- Lessons Learned

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Complexity of Industry Clinical Trial Environment

Roche Pharma Sponsored (Sole or Lead)

Roche Pharma as Supporter

“No” involvement

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Complexity of Industry Clinical Trial Environment

Pharma development (Phase 1, 2, 3 & global phase 4)

Pharma Business/Strategic Marketing (global or local)

Local affiliates

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Complexity of Industry Clinical Trial Environment

- Very wide spectrum of clinical study type/complexity
- Different approaches justified while ensuring adherence to the principles of GCP
- Such different approaches governed by common basic principles and SOPs across organizational functions

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Monitoring Objectives

More than “data” monitoring

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Monitoring Objectives

Protect the rights and well-being of human subjects

Ensure data integrity

Ensure protocol compliance

Proper control and use of IMP

Availability and archiving of essential documents

Train site staff in study specific procedures & GCP

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Monitoring procedures

Extent and form of GCP compliant monitoring

On site versus central monitoring + specified procedures

Adaptive and risk based monitoring procedures

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Adaptive Monitoring Procedures

- Fit for purpose
- Dependent on stage, scope, and complexity of trial/protocol
- Cannot compromise on safety & ethics or data integrity
- Budget not an allowable factor for inappropriate monitoring
- Risk management based strategy
- Part of acceptable QM approach

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Extent of GCP Monitoring

Must deliver appropriate study specific site training

Sites properly initiated

First visit within 6 weeks of patient enrollment

Frequency of intermittent monitoring dependent on :

- no. of patients/site
- rate of enrollment

Sites to be properly closed

Defined & justified in advance – study monitoring plan

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Challenges

Inadequate monitoring has impacted on ;

- Data quality
- Timeliness and frequency of AE reporting
- Frequency of protocol violations
- Control over management of IMP
- Availability of essential documents

With significant consequences for sponsor and patients

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Lessons Learned

- Protocols must be appropriately designed for purpose
- Importance of training for both monitoring and site staff
- Trial must be sufficiently resourced to promote adequate contact with site (before, during, and at close of study)
- Where there are limitations – identify these and take action e.g. monitoring contracted out to a CRO

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Lessons Learned

- Importance of study specific monitoring plan based on risk assessment/management
- SDV – important aspect of process directly influencing data acceptance (importance of study specific SDV plan)
- Define SD plan (with essential elements) with investigator