Building a Quality Assurance Program to Manage the Risk Associated with Investigator-Initiated Studies

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I have no conflicts to disclose
Objectives

A look at our presentation agenda

- Background
- Risk Assessment
- Program Organization
  - Prioritize Initiatives
Establish Goals / Objectives

Build Relationships

Develop Performance Metrics

Determine the Scope of Review
  - Monitoring
  - Quality Assessments
Background

Investigator-Initiated Trials (IITs)

Why Develop a QA Program for IITs?
What are the benefits?
What are the challenges?
Is it worth the investment?
Risk Assessment

- Investigational New Drugs (INDs)
- Investigational Device Exemptions (IDEs)
- IND / IDE Exempt Research
  - Multi-center
  - Single-center
- Non-interventional Research
  - Correlative Studies
  - Chart Reviews
  - Databases – Repositories
Program Organization

Evaluate Current QA Activities
- Resolve Outstanding Queries, if applicable

Assess Current QA Policies / Procedures / Templates
- Update Governing Documents and Templates, if needed

Devise a Strategic Communication Plan
- Program Creation
- OR
- Program Restructure

Program Creation

OR

Program Restructure
Program Goals / Objectives

- Expand IIT Program
- Facilitate Innovation
- Improve Trial Management
- Reduce Deviations
- Support PI Sponsored Research
- Mitigate Risk
- Facilitate Innovation
- Expand IIT Program
Develop Metrics

- Number of reviews
- Monitoring plan frequency compliance
- Number of observations
Build Relationships

- PIs and Co-Is
- Nursing
- Administration
- Pharmacy
- Coordinators
- Finance
Determine Scope of Review

- Monitoring
- Quality Assessments
- Audits
- Other
Prioritize Reviews

- IND / IDEs
- Exempt (IND / IDEs)
  - Multicenter
- Exempt (IND / IDEs)
  - New Investigator
- IITs sponsored by
  Outside Academic Medical Centers
Pilot Review Process – Monitoring

01 Review Protocol
02 Review Database
03 Review MOP
04 Connect with the Study Team
05 Develop the Monitoring Plan
06 Deliver Monitoring Plan
07 Feedback and Fine Tuning
Evaluate Review Process

- Successes
- Challenges
- Stakeholder Reactions
- Unexpected Issues
Reform Review Process

Meet the Needs of the Health System

Change is **POWERFUL**
Key Points

- Risk Assessment
- Program Organization
- Standardized Review Process
- Adaptability

Goals / Metrics
Conclusion / Reflection

“It Takes a Village”
Thank you!

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