How to Take the Risk Out of Risk Based Monitoring

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Why do we have Risk Based Monitoring?

- It is actually “Risk Based Approach to Monitoring”
- In the past, monitoring involved
  - Frequent visits
  - 100% Source Data Verification
- Resource intensive
- Systematic issues were missed
- Overall quality of data was not addressed
Key Principles of RBM

- Centralized analysis of summarized data
- Conduct risk assessment
- Define monitoring plan to address risks identified
- Identify systematic issues and target affected sites
- Frequency of on-site visits and time spent there depends on quality
Role of programmers in RBM

- Program different risk factors, including fraud detection
- Calculate overall risks of sites
- Derive monitoring tasks based on risk from monitoring plan
- Review and update checks performed based on study period
- Regularly run and review results of analysis with central monitors
Risks for programmers

• Communication with Central Monitors
• Managing analysis
  • Fraud detection
  • Check critical data
    • Consent, eligibility, randomization
    • SAEs – Chi squared tests
    • Efficacy endpoints
• Site related
  • Number of queries per page
  • Delay in entering visit data
Strategies to mitigate the risks

- Communication with CM
  - Experience over time
  - Confirm all statistical requirements with trial statistician
  - Explain back your understanding of what CM asked for
    - It will most likely be not what they want
  - Show CMs the results and ask them to explain them back
    - Their understanding of the results and presentation is critical
Strategies to mitigate the risks

IQRMP
Analysis Plan
Table Shells
SDTM/ADaM
Fraud macros
Check macros
Analysis macros
Metadata
Auto-generated analysis programs
Results database
Tables, Listings & Figures
Share with CMs/CRAs/DMs

Tables & Figures E-templates

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Summary

- There are many risks when it comes to RBM
  - Performing the correct data specific analysis to determine risk
  - Defining the appropriate response for each risk factor

- Defining a standard process can help to take the risk out of RBM
  - Use CDISC data as starting point
  - Generate a standard set of macros, one for each analysis
  - Agree standard output that is generated for all studies
  - Consistent analysis across studies will provide quality
Questions or Comments?

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