

Analyses used in 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



Assessing Quality

- Check critical data to assess if they are as expected
 - Consent, eligibility, randomization, PVs
 - SAEs – Chi squared tests
 - Efficacy endpoints
- Site related
 - Number of queries per page
 - Delay in entering visit data
 - Number of changes in key site staff



Detecting Fraud

- Check inliers and outliers
- Check when data is collected: weekends, national holidays
- Under-reporting of AEs
- Review patient profile, order of dates of key events
- Digital preference



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
- Key goals of centralized analysis
 - Assess quality of data, know your study
 - Assess quality of site
 - Standard analyses will allow comparison across studies
 - Focus monitoring on sites assessed to be of higher risk
 - Reduce quantity of data monitored at site

Questions or Comments?



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