

How to Take the Risk Out of Risk Based Monitoring

Shafi Chowdhury
PhUSE US Connect 2019, Baltimore

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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

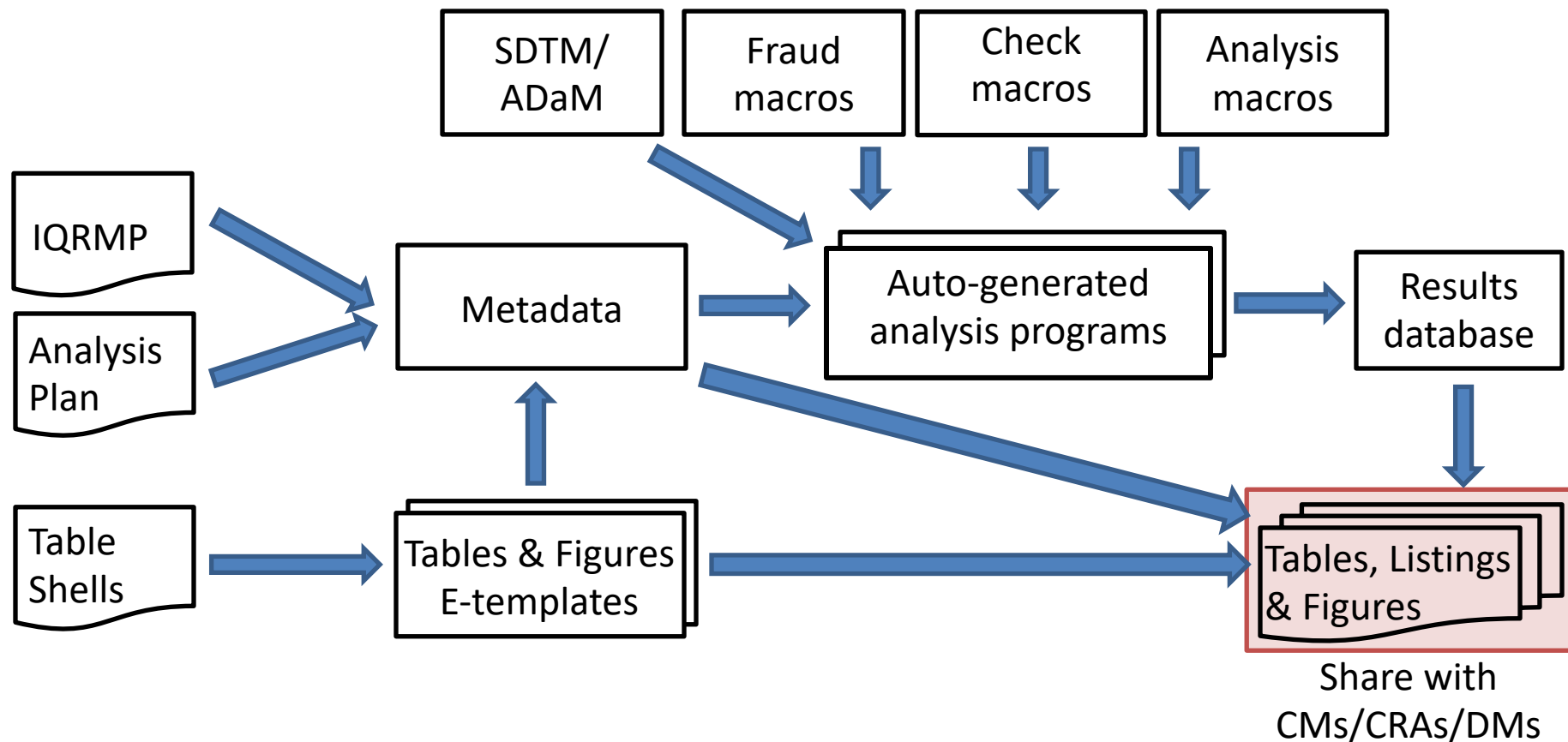
- Communication with Central Monitors
- Managing analysis
 - Fraud detection
 - Check critical data
 - Consent, eligibility, randomization
 - SAEs – Chi squared tests
 - Efficacy endpoints
- Site related
 - Number of queries per page
 - Delay in entering visit data



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



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?



Shafi Chowdhury

shafi@shaficonsultancy.com

www.shaficonsultancy.com

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