

What does Risk Based Monitoring mean to Data Management?

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Agenda

- ❑ Introduction
- ❑ Activities in scope
- ❑ Examples
- ❑ Challenges
- ❑ Best Practices
- ❑ Conclusion



Risk Based Monitoring

- ☐ What is RBM?
- ☐ How is RBM implemented?
- ☐ What are the benefits of RBM?
- ☐ What is the role of Data Management in the implementation of RBM?
- ☐ Can Data Management benefit from RBM?



Data Management activities in scope

☐ Scope in the context of RBM implementation

☐ Standard activities

- Data Management plans
- CRF Development/Database setup /Mapping
- Database Freeze/Lock?archival

☐ Customisable activities

- CRF Design
- Data Review/Validation Plans (Checks & Listings)
- Data Cleaning/Querying
- Reconciliation of external Data



CRF Design

SDV & SDR

Example: ICF & Eligibility Criteria – GCP Compliance

ID number	Critical data & processes		Risk ID (if applicable)	Key Risk Indicator(s) used for risk detection (if applicable)	RBM strategy		
	List the Critical data and Critical processes	Provide Rationale			CENTRAL MONITORING	LOCAL MONITORING	
						SDV Critical data to be verified	SDR Clarify what needs to be reviewed
1	ICF	GCP compliance	NA	NA	Trial Monitoring report PD report, Standard listing	<u>Inform consent screen</u> ; Informed consent date	Ensure original signed and dated ICF is present for each subject & correct version is used. Ensure evidence of consenting process (in compliance with ICH-GCP and relevant SOPs)
2	Eligibility Criteria	GCP compliance	NA	NA	PD report Standard Listing	<u>Demography screen</u> ; Date of birth <u>Eligibility check form</u> ; Inclusion and exclusion criteria	Review source to ensure protocol compliance with inclusion/exclusion criteria Ensure PI review of screening sample lab reports and review of the lab values



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CRF Design (Capture what matters)

- ☐ Primary, Secondary and Tertiary end points
- ☐ Eligibility Criteria assessments
- ☐ Baseline assessments



Data Review/ Data Validation Plan

- ☐ Online Checks, offline Checks and Listings
- ☐ Standard v/s Specific
- ☐ Checks v/s Listings
- ☐ Manual Cleaning



Data Cleaning and Data Querying

- ❑ Data Cleaning & Query resolution plan
- ❑ Define scope of cleaning & querying
- ❑ Issue queries that matter
- ❑ Always within the scope of study milestones



Reconciliation of External Data

- ❑ Not all external data comes from one source
- ❑ Type and source of data should drive the reconciliation

Example: Safety Blood Sampling

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5	Blood sampling process for hematology and biochemistry	Primary Objective: safety	6	NA	PD report Trial Monitoring report Reconciliation listings to flag issues Standard listing	Blood sampling screen: All fields	Samples has been taken according to study procedures. Sample labelling is done as described in SPM. Samples has been taken at the correct timepoint Safety samples are shipped daily



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Reconciliation of External Data

- ❑ What about non critical data?
- ❑ Ex: Sample storage for future research



Challenges

- ☐ What about the non-critical data?
- ☐ Change in mindset
- ☐ Agreement on the approach



Best Practices

- ☐ Team Work
- ☐ Continuous and conscious effort to work together
- ☐ Customized plans at study level
- ☐ Agreement on approach from all the stake holders
- ☐ **Focus on absence of errors that matter!**



Conclusion

- ❑ Focus should always be on data quality and subject safety
- ❑ Resourcing of time and efforts should be driven by data that matters
- ❑ Think before we act
- ❑ **Shift in mindset, right strategy and good team collaboration will enable economic efficiencies!**



Thank you!

Questions?

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