



Strategies for Clinical, Data and Statistical Team Integration and Planning to Improve Data Quality and Mitigate Risk

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Agenda

- Early Considerations for Risk-Based Monitoring
- Development of Project Plans
- Team Integration and Communication
- Clinical Site Quality Management
- Web Portals in Data Surveillance and Study Management
- Q & A



Early Considerations for Risk-Based Monitoring

- Discussions during project planning for RBM strategy
 - Does RBM make sense for this trial?
- Effective resource and budget planning
 - Functional area team members and FTEs
 - Number and frequency of on site visits
 - Centralized monitoring efforts
 - Lessons learned from similar trials
 - Site Selection



Early Considerations for Risk-Based Monitoring

Protocol
Complexity

Data
Collection
Methods

Critical
Endpoints

Planned On
Site Frequency

Trial Duration

Number and
Experience of
Clinical Sites

Safety
Concerns and
Assessments

Compound
and TA
Experience



Risk Management Planning and RBM

- Brainstorm potential scientific and procedural risks
- Build CMP to adapt monitoring as needed
- Assign categories or risk potential
- What level/incidence rate triggers a shift?
- Both site level and subject level



Risk Management Planning and RBM

- Determine communication pathways
 - Sponsor and CRO partners
 - Across functional areas
- Determine mitigation strategy for each potential risk
- Regular discussions with Sponsor and CRO project monitoring leadership
- Early escalation and remediation of issues
- Documentation of decisions and actions!



Development of Clinical Monitoring Plan

Traditional CMP

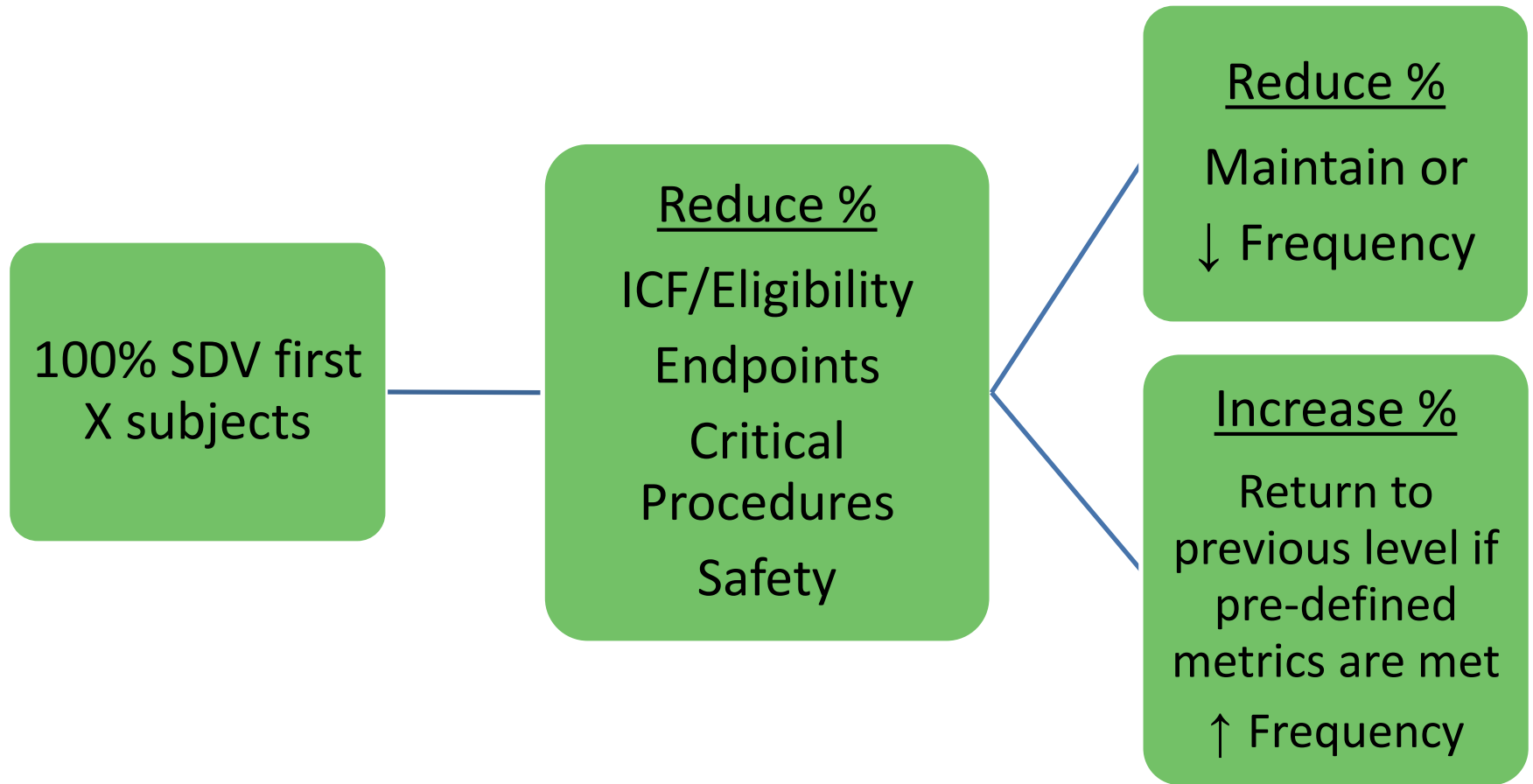
- 100% SDV
- Same plan for all sites
- Static monitoring throughout study
- Analysis after OSM

RBM/Adaptive CMP

- <100% SDV
- Tailored approach
- Adjust approach with pre-defined metrics
- Ongoing central data surveillance with DM/Stats



Development of Clinical Monitoring Plan



Centralized Monitoring

Scientific Aspects:

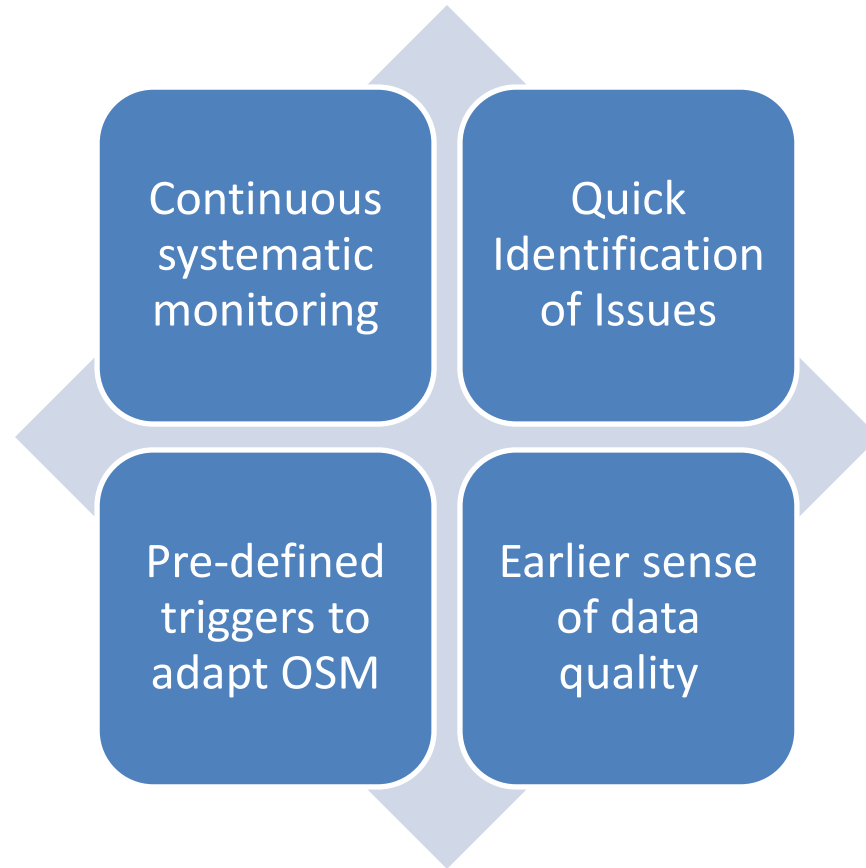
- Eligibility
- Safety – AE/SAEs
- IP
- Central Lab/ECG
- Key Efficacy Variables

Procedural Aspects:

- Enrollment
- Visit Completion
- PRO Completion
- Protocol Compliance Issues
- Data Entry
- Query Management/Status
- IVRS/IWRS



Centralized Monitoring



Team Integration and Communication



Team Integration and Communication

- Establish strong communication pathways, early on
 - Training for team members and sites
 - Standing and ad hoc telecons
 - Tools for tracking and management: The RAMM
- Cross-functional team members involved at all stages
- Enhanced programmable reporting to inform OSM and maximize on site efficiency



Site Level Quality Management

- Assessment of site level QM efforts at SQV
- QM Training
 - General
 - Site specific
- QM Plan Development
 - Evolves over course of the trial



Site Level Quality Management



Site Level Quality Management

Indicator(s)	Criteria	Subject # _____	Subject # _____
		Yes/No/NA	
Informed Consent and Assent Process and Documentation	Current, approved version(s) of the Consent and/or Assent Document has(ve) been signed and dated in ink by participant or legally authorized representative and, if required, appropriate site staff or witness.		
	Documentation in subject's record or medical chart regarding the process/components of informed consent is present, including: the participant and/or legally authorized representative received a full explanation of the study, and adequate time was given for consideration and questions regarding study participation.		



Site Level Quality Management

- QC Activities
 - Overall GCP/ICH compliance
 - Trial-specific compliance
- Root Cause Analysis and CAPA
- QM Reporting - options
 - Central review between visits
 - On site review and follow-up during monitoring visits



Site Quality Management

- Tools to assist site teams:
 - Quality Management Plan Template
 - Site-Wide Review Tool
 - Subject-Level Review Tool (see sample)
 - Summary Report



Use of Web Portals in Risk-Based Monitoring

- Dashboards
- Status Reports
- Monitoring calendars, metrics
- Trial document development
- Access tailored to role on trial



Q & A

