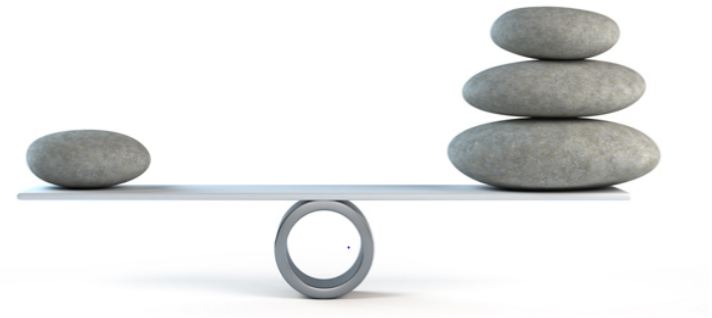


Visualizing Key Performance Indicators for Risk based monitoring



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Risk based monitoring



Realigned Focus

- No value from 100% Source Data verification conducted by monitors through on-site monitoring
- Regulatory guidance release increased industry focus towards better way of monitoring
 - EMA Reflection paper on risk based quality management for clinical trials
 - FDA Guidance for industry oversight of clinical investigations
 - PMDA's basic rules of the risk-based approach to monitoring clinical trials



Risk based Approach

- Goals
 - Data Quality
 - Patient Safety
 - Productivity
- Strategy
 - Quality by Design – Protocol & Related Plans
 - Integrated Quality Risk Management Plan (IQRMP)
 - Revised monitoring plan
 - Increase in Centralized monitoring
 - Need based On-site monitoring



Monitoring Plan

- Critical data (Endpoints of interest, Patient Safety)
- Key risk/quality/performance indicators 
- Potential error types and associated remedial actions and
- Allowable Threshold for error rates and Triggers
- Remote SDV approach & Segmentation
- Trigger based monitoring

Key Performance Indicators

Key Performance Indicators (KPI) are measures of error rates and data quality that are designated as important for management of the current study.

- What do you want to measure depends on what do you want to achieve?
- Revisit the goals
 - Data Quality
 - Patient Safety
 - Productivity

KPI – Snippets

- Data Quality
 - CRF Completion
 - Query Rate
- Patient Safety
 - Patient Profile
 - (TEAE) Vs Non – TEAE
 - Expected Vs Unexpected AE
 - Top N sites with SAE Count
- Productivity
 - Recruitment trends
 - Protocol Deviation

Demo



Thank you



Questions:

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