Cyntegrity Germany GmbH

RBM EVALUATION CHECKLIST

VERSION 2.7

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Risk-Based Monitoring (RbM) Service Checklist

A checklist for evaluation of how genuine an RbM service is.

Overview

The RbM checklist ensures that a service provider applies GCP and RbM best-practice criteria in the centralized monitoring approach.

Overall

☐ Is RbM data-driven and evidence based?

☐ Does RbM include the information from the main recording systems of a trial: CTMS, EDC, pharmacovigilance, lab data, etc.?

☐ Does the RbM analysis run on a regular basis during a trial?

☐ Is the risk mitigation strategy prepared before a clinical trial starts?

☐ Is the protocol adapted to the centralized monitoring approach?

Risk mitigation strategy

☐ Does the monitoring plan describe the centralized monitoring approach, the percentage of on-site and centralized monitoring, and the underlying decision criteria? Does the monitoring plan show, which approach is applicable to which situation?

☐ Does the risk mitigation strategy include such risk families as

☐ safety, ☐ protocol compliance, ☐ timelines, ☐ trial-specific risks, ☐ sponsor-specific risks, and ☐ fraud detection?

☐ Does the risk mitigation strategy include corresponding Key Risk Indicators (KRIs), Key Performance Indicators (KPIs) and Key Quality Indicators (KQIs)?

☐ Were the KRIs, KPIs, KQIs validated? Do any validation documents and test reports exist?

☐ Were the expectations and thresholds for the KRIs, KPIs, and KQIs clearly defined? Were the assumptions clearly documented?

☐ Was a plan prepared about regular assumptions and thresholds review during a trial?

☐ Is it defined in SOPs or SWIs who is responsible for the review and adaptation, if needed, of the assumptions, KRIs' weights? How frequently?

Technology

☐ Does technology used for RBM integrate data from multiple recording systems? (e.g. CTMS, EDC, IVRS etc.)

☐ Does the technology include customized alert capabilities?

☐ Does the technology provide trending capabilities?

☐ Does the technology provide actionable TODO plan for mitigation of risks?

☐ Does the technology integrate the experience of CRAs and study teams?

Data quality (KQIs)

☐ Is clinical data quality assessed in the RbM procedure? How frequently? Based on which Key Quality Indicators (KQIs)?

☐ Was a person defined, who will be responsible for review of data quality? How regular will the data quality review occur?

☐ Are the KQIs development dynamics and/or forecast models included in the data quality assessment?

☐ Is it defined in the monitoring plan, which communication channel is more appropriate for CRAs in which situation?

☐ If any RbM IT tools are in use, are those validated and CFR 21 part 11 compliant?

Site performance monitoring

☐ Is the assessment of site performance part of the risk-based approach?

☐ Is the assessment actionable, i.e. does a to-do plan exist which could be executed if something goes wrong?

☐ Are the sites involved in the performance and quality assessment, do they get feedback, is the process transparent to them?

Data quality assessment

☐ Are the quality thresholds defined and validated before a trial starts?

☐ Is an action plan prepared if the data quality starts getting worse?

☐ Is it clear enough, which data quality benchmark a trial targets, e.g., which confidence intervals? Based on which assumptions?

☐ Is the information from previous similar trials incorporated in the assessment of the quality criteria of the upcoming trial?

RbM process integration

☐ Does a process integration plan exist for the adoption of the RbM approach within a CRA team?

☐ Has the role of a central monitor (cCRA) been defined?

☐ Do CRAs receive appropriate training on the RbM approach?

☐ Does a plan exist, how to deal with resistance in the team?

☐ Is a team of "early adopters" among CRAs involved in process definition and integration?

☐ Are regular follow-up meetings planned during a trial?

Audit and archiving

☐ Is it possible to export risk management information at the end of a clinical trial? When, which and by whom was a risk identified and which actions were taken accordingly?

☐ Was the communication in the CRA team about the risk mitigation documented and available for a potential audit?

☐ Will the risk management information be exported for archiving purpose? For how long?

☐ Will subsequent clinical trials benefit from the lessons learned in upcoming trials? How will be the experience documented and in which format will it be available in the next trials?