# Model Approach for Risk-Based Monitoring

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### MODULES / LESSONS

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About This Guide

What’s the purpose of this guide?
This trainer guide provides a master reference document to help you prepare for and deliver the *Model Approach for Risk-Based Monitoring* training program.

What you will find in this guide?
This trainer guide is a comprehensive package that contains
- checklists of necessary materials and equipment
- presentation scripts and key points to cover, and
- instructions for managing exercises, case studies, and other instructional activities regardless of delivery method (in-person classroom, webinar or a blended classroom environment).

How is this guide organized?
Refer to the introductory materials: About this Guide within the Trainer Guide for Module 1 for further details on how this guide is organized, graphical cues and overall program information.
Module 5: Transitions

Goal
The goal of this module is the application and considerations of RBM plan implementation. In this section we will address a practical approach to implementation and management, as well as how to transition projects, protocols and sites into the RBM model.

Time
90 minutes

Overview
This module is a combination of presentation of material and facilitated “challenge” exercises for the participants.

Some slides within this module are hidden content for trainer determination of whether or not they are necessary to show during the course.

Materials Needed
- Participant Workbook (one per participant)
- Post-it notes available on each table (for face-to-face sessions)
- Flipcharts & Markers (one per every 2 tables – for face-to-face sessions)
- Multi-Colored Index Cards labeled as follows (one per person for face-to-face sessions):
  - Red – marked with a large A
  - Green – marked with a large B
  - Yellow – marked with a large C
  - Orange – Marked with a large D
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Module 5: Introduction

Welcome to Module 5 of the course on the TransCelerate Risk-Based Monitoring methodology.
Module 5: Introduction

Course Program Overview

The course information will be broken down into five distinct modules. While information may overlap, the intent is to individually explore the concepts, tools and implementation of evaluating risk and implementing management and monitoring techniques. Each module will consist of three to four key objectives, broken into lessons.

The modules are as follows:

Module 1- Introduction to Risk-Based Monitoring (RBM).
In this module we will introduce the concept of RBM, how it varies from traditional monitoring approaches and why the industry is focusing on implementing this methodology. We will also introduce you to definitions and assumptions underlying the TransCelerate Position Paper: Risk-Based Monitoring Methodology that was published May, 2013.

Module 2- Methodology and Team Members.
The focus of module 2 will be to further explore the TransCelerate Methodology, introduce the RBM toolkit, discuss RBM team responsibilities within a company, and describe the on-site, off-site, and central monitoring activities in study oversight.

Module 3- Risk Assessment.
In module 3 we will be focusing on how to identify and quantify risk and will address one of the key measurement tools, the RACT, in detail.

Module 4- Risk Management.
Module 4 will further address risk management and how to define critical Risk Indicators and Thresholds in decision-making. We will also talk about risk mitigation plans, activities, and risk response.

Module 5- Transitions.
The focus of the final module is on the application and considerations of RBM plan implementation. In this section we will address a practical approach to implementation and management, as well as how to transition projects, protocols and sites into the RBM model.
Module 5: Introduction

Module 5 Objectives

Upon completion of this module, learners will be able to...

1. Inform investigative sites about the Risk-Based Monitoring (RBM) model
2. Describe metrics used to measure the impact of the proposed methodology
3. Apply effective transition techniques for studies and sites
4. Discuss challenges with implementation within different cultures and systems

Direct participants to the Participant Workbook

Module Objectives

In this module, we will be discussing various aspects related to the implementation of the RBM methodology.

Review module objectives on the slide
The success of a company’s implementation of the RBM model into clinical trials may be influenced by the acceptance of the new methodology by investigative sites. Therefore, informing sites about the RBM model and the model’s benefits for site activities is a key step in implementation of the methodology.
Inform Investigative Sites about RBM Model

Slide 6

What Investigative Sites Need to Know

- Background:
  - Traditional monitoring description
  - Drivers for change
  - Regulatory/industry movement
- RBM description
- Benefits to sites
- Positive outcomes
Inform Investigative Sites about RBM Model

What Investigative Sites Need to Know

Informing investigative sites about the RBM model requires covering the following topics.

1. First, we want to provide some background to site personnel to “orient” them to industry perspectives surrounding monitoring and movement toward a risk-based approach.

2. Then, we will describe and define what risk-based monitoring is and how it is different from “traditional” monitoring. This should include a discussion of how these principles bring benefits to sites.

3. Next, we want to outline the positive impacts that this model has for sites, their workflow, and priorities.

Investigators may feel that the sponsor will have less contact with the site after RBM has been implemented and may feel uncomfortable about it. When explaining the process, it is critical to remind the site that the sponsor can always be contacted whenever needed. Consequently, communication is the key.

IMPORTANT NOTE

The remaining slides (numbers 5-18) within this section of the module are not designed for delivery to an audience of investigators and site personnel. They are intended to be used as training materials to prepare monitors and internal staff for discussing site concerns regarding RBM.

There is a separate deck that will be utilized to inform sites about the transition to RBM including:

- What RBM is
- Rationale for change
- Impact to site
- Benefits for site.
Inform Investigative Sites about RBM Model

Traditional Approach: On-Site Monitoring

In person evaluation carried out by sponsor/CRO personnel at the investigative site location to:

- Identify missing data in source records and data entry errors in case report forms
- Assess compliance with protocol and investigational product accountability
- Evaluate Investigator supervision
- Review essential documents
Inform Investigative Sites about RBM Model

On-Site Monitoring – Traditional Approach

We generally think of traditional site monitoring as an approach consisting of monitoring all data, in-person, while on-site.

Traditional on-site monitoring can be defined as an in-person evaluation carried out by sponsor or CRO representatives at the location where the study is being conducted.

The visits have been generally conducted based on a set schedule (such as every four to six weeks) and 100% of data is source verified regardless of the type of study, safety risks, phase of the study, stage of the study, or experience of the individuals conducting the study.

On-site monitoring is conducted to identify missing data in source records and data entry errors in case report forms, assess compliance with protocol and investigational product accountability, to evaluate investigator supervision, etc.

While the use of this approach has been widespread in the industry, it has presented challenges for both sponsors/CROs and for investigative sites.

Inform Investigative Sites about RBM Model

Slide 8

**Discussion Point**

What challenges does the traditional monitoring approach present for sites?

**Group Discussion**

Facilitate a group discussion about the challenges traditional monitoring approaches present for sites.

**Facilitating the Activity**

Allow 5 minutes for this activity

*Classroom OR Webinar Workshop Participants (face-to-face OR online)*

Ask participants to offer their thoughts as a large group (raising their hands OR for face-to-face participants you could have discussions at the tables).

Document responses and ideas on a physical flipchart or virtual whiteboard.
Inform Investigative Sites about RBM Model

Discussion Debrief

Possible challenges to be highlighted during discussion:

- Protocol deviations or errors in protocol interpretation/performance are not identified until the on-site visit occurs; the errors, therefore, tend to recur multiple times, possibly impacting subject safety and data quality
- Having sponsor personnel frequently on-site distracts personnel from daily work activities
- Investigative site personnel spend a lot of time with sponsor personnel during on-site visits; this can interfere with their ability to recruit subjects into trials or conduct study visits

Those challenges have also been recognized by industry and regulatory authorities. The following slides will provide some insights on their perspective.
Inform Investigative Sites about RBM Model,

Industry Perspective on Changing Our Approach to Monitoring

Various Reasons for Change

- Complex Protocols
- Limited Resources
- Cost-Benefit Ratio
- Risk Mitigation
- Adapt to Needs
- New Technology
- Regulatory Shift
Inform Investigative Sites about RBM Model,

**Industry Perspective**

From the sponsor perspective, there may be multiple and varied reasons for changing our approach to monitoring. The rationale for change may vary depending upon everything from the size of the sponsor to the type of study being conducted.

The endorsement of a change in monitoring by key regulatory authorities serves as a rationale for looking at monitoring in a different way. These regulatory authorities are communicating that monitoring can and should be designed and customized to meet the specific needs of the program and study.

Some challenges facing the industry, such as protocol complexity, focus on cost-benefit ratio, and limited resources, just to name a few, are also serving to help drive a shift in our monitoring philosophy.

Finally, changing our monitoring approach potentially provides benefits such as improved risk mitigation, adapting monitoring to the needs of the trial or site, and more effective use of current state of the art technology.
Inform Investigative Sites about RBM Model,

Risk-Based Monitoring (RBM):
Industry Movement

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<th>FDA Guidance</th>
<th>EMA Reflections Paper</th>
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<td>Quality Clinical Trial Data</td>
<td>Risk Based Quality Management</td>
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<tr>
<td>• Change approach</td>
<td>• Assess Risk</td>
<td>• Plan</td>
</tr>
<tr>
<td>• No single approach is appropriate</td>
<td>• Combination of monitoring activities</td>
<td>• Adapt</td>
</tr>
<tr>
<td>• Tailor monitoring approach</td>
<td>• Tailor Monitoring Plan</td>
<td>• Build on experience and advances</td>
</tr>
<tr>
<td>• Protocol quality impacts monitoring quality</td>
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Industry Movement

Because of the challenges we’ve reviewed with the traditional monitoring approach, there has been movement towards what is called Risk-Based Monitoring within the clinical research industry over the past couple of years.

Three key initiatives include a report from the Clinical Trials Transformation Initiative, the FDA Guidance for Industry: A Risk-Based Approach to Monitoring, and the EMA Reflection Paper on Risk-Based Quality Management in Clinical Trials.

These three documents provide a framework for some of the concepts that are driving the industry to change. We will not be spending a great deal of time discussing these documents, but it is important to understand that there is a regulatory drive to adapt clinical trial practices according to risk and move away from the idea of “one size fits all”.
Inform Investigative Sites about RBM Model,

Document Summaries

The CTTI project focused on gathering data, confirming the current industry approaches to monitoring, and verifying that our primary focus should shift from post-hoc inspection to incorporation of quality into the scientific and operational design of a trial. CTTI stated there is not one single approach that is appropriate or necessary in all circumstances, and that the monitoring approach for a given clinical trial should be tailored to the needs of the trial and may combine several methods of monitoring. Furthermore, the CTTI participants agreed that the quality of the protocol is likely an important determinant of the quality of monitoring.

The FDA Guidance was intended to assist sponsors in developing risk-based monitoring strategies and plans tailored to the specific human subject protection and data integrity risks of the trial. It included a focus on critical study parameters, encouraged the use of a combination of monitoring activities and promoted greater reliance on centralized monitoring practices, where appropriate.

The EMA Reflections Paper focused on Risk-Based Quality Management through assessment of the use of risk identification and control. The key points were to develop a plan at the start of a program, adapt protocol by protocol, build on experience gained with each study and build on technical, regulatory, and other advances.
Inform Investigative Sites about RBM Model,

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As of November 2013

- Abbvie
- Astellas
- AstraZeneca
- Biogen Idec
- Braeburn Pharmaceuticals
- Boehringer Ingelheim
- Bristol-Myers Squibb Company
- CUBIST
- EMD Serono
- Forest Laboratories, Inc.
- GSK
- GSK
- Johnson & Johnson
- Lilly
- Onyx Pharmaceuticals
- Pfizer
- Roche
- Sanofi
Inform Investigative Sites about RBM Model

Member Companies

TransCelerate BioPharma Inc. is an independent non-profit organization focused on accelerating the development of new medicines.

- TransCelerate was founded with a mission to identify and solve common drug development challenges with the end goals of improving the quality of clinical studies and bringing new medicines to patients faster.
- TransCelerate was launched on September 19, 2012. At that time, the organization chose to focus on five initiatives related to clinical trials – designed to increase efficiency, reduce costs and enhance subject safety. One of these 5 initiatives is to develop a methodology for implementing Risk-Based Monitoring into clinical trials.

As you can see a number of industry leaders are members of TransCelerate and have contributed to identifying and capturing efficiencies across the industry. This is an unprecedented industry collaborative effort that is fully supported and encouraged by the FDA and the EMA. For example, FDA representatives reviewed the RBM position paper and provided feedback prior to its publication and release.

RBM: Potential Discussion Points with Sites

An adaptive approach to clinical trial monitoring that directs monitoring focus and activities to the evolving areas of greatest need which have the most potential to impact subject safety and data quality.

- Focus monitoring on data/processes that matter most
- Share responsibility for subject safety and data quality
- Customize monitoring to the needs of the trial
- Use technology to quickly identify and resolve issues
- Adjust activities in response to findings

RBM Principles
Inform Investigative Sites about RBM Model,

Direct participants to the Participant Workbook

IMPORTANT NOTE
Next slides will illustrate the benefits to sites from RBM implementation.

Potential Discussion Points with Sites – RBM Principles

Risk-based monitoring (RBM) is an approach that focuses monitoring attention and activities so that areas with the most significant impact to subject safety and data quality can be identified and corrected. RBM methodology relies on a concept which is called “Quality by Design” (QbD).

This concept indicates that Critical Data and Processes are already considered during Protocol and CRF preparation.

Module 1 of the TransCelerate RBM training ("Introduction to Risk-Based Monitoring") gives some more details about this concept. The core principles of RBM include:

• Monitoring activities are designed to focus on the data that is critical to satisfy study objectives, protect the safety of subjects, and/or ensure regulatory compliance
• Shared responsibility for subject safety and data quality exists; investigators are responsible for their site’s data quality and are expected to partner with the Sponsor to address, resolve, and prevent issues
• Customize the monitoring approach to each trial based on risk assessment; includes greater reliance on central/off-site monitoring and expanding the concept of monitoring to a cross-functional responsibility
• Use of all available technology to allow sponsors to supervise study conduct without having to be at the site location; this allows for more rapid identification and resolution of potential issues
• Adapt the monitoring approach and activities as required in response to risks or issues that evolve during the trial; includes a more targeted approach for on-site monitoring visits (these are data driven not interval driven)
Inform Investigative Sites about RBM Model,

Make the following key points:

- This conveys to investigative sites the core principles of RBM
- RBM methodology relies on a concept which is called “Quality by Design” (QbD).

RBM: Potential Discussion Points with Sites (continued)

- Focus monitoring on data/processes that matter most
- Share responsibility for subject safety and data quality
- Customize monitoring to the needs of the trial
- Use technology to quickly identify and resolve issues
- Adjust activities in response to findings
- Reduction in amount of source data verification
- More targeted source data verification
- Source data review performed to evaluate site processes
- Shift of priorities during on-site monitoring

Direct participants to the Participant Workbook
Inform Investigative Sites about RBM Model,

Discussion with Sites: Monitoring

Monitoring activities in the RBM model are designed to focus on Critical Data that protect subject safety, ensure data integrity/reliability and protocol/regulatory compliance.

Sites benefit in these ways from this refocusing of monitoring activities:

- Shift from 100% source data verification (SDV) to performing SDV on a reduced percentage of data
- Perform SDV in a more targeted way to address key data, certain processes, or identified issues
- Perform source data review (SDR) in conjunction with SDV. SDR represents a review of subject source documents in a holistic sense and provides a means of reviewing the processes by which the data were collected. For example, SDR allows for evaluation of investigator involvement, protocol compliance such as in regards to investigational product, laboratory procedure compliance, and the ICF process, etc. This can provide additional assurance of data integrity
- During on-site monitoring, the priorities of review conducted by sponsor personnel change. There may be less focus on SDV and more focus on the process of data collection
Inform Investigative Sites about RBM Model,

Slide 14

RBM: Potential Discussion Points with Sites (continued)

- Focus monitoring on data/processes that matter most
- Share responsibility for subject safety and data quality
- Customize monitoring to the needs of the trial
- Use technology to quickly identify and resolve issues
- Adjust activities in response to findings

- Investigators expected to take “ownership” of data
  - Timely data entry
  - Identify causes of problems when they occur
  - Take action to prevent recurrence of errors
  - Opportunity for site quality assurance

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Direct participants to the Participant Workbook
Inform Investigative Sites about RBM Model,

Discussion with Sites: Subject Safety & Data Quality

In the RBM methodology, there is recognition that all research stakeholders (not just sponsors) share responsibility for subject safety and data quality.

Therefore, monitoring and quality assurance are not just sponsor activities. Investigators are responsible for their site’s data quality and are expected to partner with the sponsor to address, resolve, and prevent issues.

Investigative sites, therefore, benefit in these ways:

- Expectation for Investigators to “take ownership” of their data and not rely on monitoring to find errors or problems
  - Entering study data in a timely manner allows for timely identification of potential safety signals and promoting subject safety
  - When errors are identified, sites should identify the underlying cause of the problems
  - Corrective and preventive actions should be implemented to prevent recurrence of problems or errors
- Investigative sites will have the opportunity to develop their own quality assurance or internal auditing activities
Inform Investigative Sites about RBM Model,

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RBM: Potential Discussion Points with Sites (continued)

- Focus monitoring on data/processes that matter most
- Share responsibility for subject safety and data quality
- Customize monitoring to the needs of the trial
- Use technology to quickly identify and resolve issues
- Adjust activities in response to findings

- No fixed schedule of on-site monitoring
- Many different sponsor personnel may perform monitoring activities
- More central and off-site monitoring

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Direct participants to the Participant Workbook
Inform Investigative Sites about RBM Model,

Discussion with Sites: Customize Monitoring

As sponsors/CROs customize the monitoring approach to each trial based on the specific needs of the trial, investigative sites can see these benefits:

- On-site monitoring will be less likely to occur on a fixed schedule or interval during the study.
- Investigative site performance will be monitored by many different sponsor personnel, not just Clinical Research Associates or those considered “traditional monitors”. This broader review results in increased subject protection and data quality.
- More monitoring will occur through central and off-site activities. RBM uses a “comprehensive monitoring" which includes central, off-site, and on-site activities designed in accordance with the program and study needs.
Inform Investigative Sites about RBM Model,

**Slide 16**

RBM: Potential Discussion Points with Sites (continued)

- Focus monitoring on data/processes that matter most
- Share responsibility for subject safety and data quality
- Customize monitoring to the needs of the trial
- Use technology to quickly identify and resolve issues
- Adjust activities in response to findings
- Greater use of technology
- Timely data entry and query resolution
- Data reviewed off-site and sites contacted to resolve issues remotely
- Central monitoring to compare data and identify issues

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Direct participants to the Participant Workbook
Inform Investigative Sites about RBM Model,

Discussion with Sites: Use Technology

RBM involves the use of all available technology to allow sponsors to supervise study conduct without having to be at the investigative site location and to identify and resolve potential issues in “real time.”

This benefits sites in the following ways:

- Increasing reliance on technology, not only through a broader use of Electronic Data Capture (EDC) systems but other electronic tools and systems (e.g., subject diaries, interactive technology for randomization, etc.) has the potential to reduce paperwork, redundancy, and errors.
- Timely data entry into these electronic systems allows for timely data review by the sponsor in an ongoing manner. Therefore, queries can be addressed in “real-time.” RBM should effectively reduce the burden of query resolution at the conclusion of a trial as more data is being reviewed remotely allowing for more timely query generation and issue resolution. Sponsor expectations for data entry and query resolution may detailed in the clinical trial agreement or contract with the investigative site.
- If issues are identified through central or off-site monitoring, sites may be contacted to resolve those issues through remote means. For example, re-training to clarify protocol expectations may occur through a teleconference.
- Central monitoring will be performed to evaluate risks and search for issues, by comparing data across investigative sites, subjects, countries and protocols.
Inform Investigative Sites about RBM Model,

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RBM: Potential Discussion Points with Sites (continued)

- Focus monitoring on data/processes that matter most
- Share responsibility for subject safety and data quality
- Customize monitoring to the needs of the trial
- Use technology to quickly identify and resolve issues
- Adjust activities in response to findings

- Teleconferences to discuss central/off-site monitoring findings
- Data, findings, or study events may “trigger” on-site monitoring
- Monitoring adjusts during study as risks change

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Direct participants to the Participant Workbook

Discussion with Sites: Adjust Activities

Finally, within a RBM model, sponsors adapt the monitoring approach and activities for each trial, and potentially for each investigative site, as required in response to risks or issues identified during the trial.

Sites, therefore, may benefit in these ways:

- Potential issues found during central or off-site monitoring can be investigated and discussed when necessary through teleconferences, thereby minimizing disruption to investigative site workflow
- On-site monitoring may occur when “triggered” by certain data, findings, or changes in the study, maximizing value for sponsors and sites
- Monitoring activities may vary during the course of a study as the risks change, focusing sponsor and investigative site resources where they are most needed
Inform Investigative Sites about RBM Model,

Slide 18

Challenge Yourself

Which of the following statements reflects a potential impact to investigative sites from the adoption of Risk-Based Monitoring (RBM)? (select all that apply)

A. Sites will no longer be required to accommodate on-site monitoring.
B. Sites may be expected to audit or perform quality checks on their own data.
C. Sites will be required to attend daily teleconferences with sponsors to discuss central monitoring findings.
D. Sites can expect a greater use of technology and electronic systems in clinical trials.

Challenge Yourself

Let’s see how much we know about the impact of RBM to investigative sites.

IMPORTANT NOTE

Answer key is on the next slide.

Facilitating the Activity

Classroom Workshop Participants (face-to-face)

Ask participants to use the colored / labeled index cards at their table and hold up their answer choice(s). This will allow you to see quickly what the majority of the room responds with.

- A = Red with an A written on it
- B = Green with a B written on it
- C = Yellow with a C written on it
- D = Orange with a D written on it
Inform Investigative Sites about RBM Model,

**Webinar Workshop Participants (online)**

If possible, utilize your polling options within your webinar provider. Create a poll and pull it up within the meeting room, ask participants to vote on their answer.

Ensure you have the poll set for multiple correct answers.

You can also use additional capabilities within your webinar provider such as status icons, or the chat features.

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**Slide 19**

You may choose to show the slide with the correct answers

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**Challenge Yourself Debrief**

Answers are B and D.

A is not correct because there is generally an expectation of some level of on-site monitoring for most trials. For example, at the beginning of the study, an important early activity is to ensure Critical Processes are being followed and subjects are being properly enrolled. This typically requires on-site monitoring.

C is not correct because a routine of scheduled daily teleconferences to discuss issues is not aligned with the RBM concept of monitoring resources and activities aligning with risks.
Inform Investigative Sites about RBM Model,

**Slide 20**

**Potential Benefits for Investigative Sites**

- Subject safety is maintained
- Problems are solved before they recur
- Personnel can focus on core job functions
- Investigative sites are inspection-ready
- Site quality is enhanced
- Timely decision-making and communications

**Benefits for Investigative Sites**

As sponsors shift to a RBM model, there are definitely some potential benefits for investigative sites.

- First of all, subject safety is maintained and possibly enhanced through RBM because key safety data are being reviewed in a more “real-time” manner.
- Secondly, problems are solved before they recur in the study through early identification of issues and near “real-time” data query resolution. RBM should prevent the problem of data queries being issued months or years after the data was generated.
- With less frequent, regular on-site monitoring visits, site personnel may be freed up to focus on their core job functions.
- Investigative sites are inspection-ready as a result of the enhanced expectations for the completion of corrective and preventive actions when issues arise.
- Finally, sites may see increased quality as RBM expectations promote increased Investigator involvement and internal quality assurance activities.

Other benefits may include: Reduction in number of queries in theory because issues in data are addressed earlier, sites that need more focus get it and sites that need less have more time as less CRA visit burden.
Metrics to Measure Impact

Module 5: Objective 2

METRICS TO MEASURE IMPACT OF THE RBM METHODOLOGY

Introduction Objective 2

Technology enables comprehensive measuring of the monitoring process and oversight activities.

 Metrics can be developed to measure the effectiveness and efficiency of the new RBM process.
Metrics to Measure Impact

Slide 22

Defining Metrics

Standards of measurement by which efficiency, performance, progress, or quality of a plan, process, or product can be assessed.

- Measurement
- Applied to quantifiable aspect of performance
- Used for decision-making

Source: BusinessDictionary.com

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Direct participants to the Participant Workbook

Defining Metrics

So what are metrics?

- BusinessDictionary.com defines “metrics” as seen on the slide [read definition].
- Another way to think about a metric is that it is any type of measurement used to evaluate some quantifiable component of a company’s performance.
- A valuable metric should allow the company to make better business decisions and allow comparison, for example, to the metric obtained from a different approach or from an industry benchmark.

Reference:
http://www.businessdictionary.com/definition/metrics.html#ixzz2a5aA5Zkm
Metrics to Measure Impact

Slide 23

Evaluating RBM

Dimensions to Assess

- Quality
- Timeliness/Cycle Time
- Efficiency

What Do You Think?

Can you identify at least one metric within each dimension to evaluate the effectiveness of the RBM methodology on clinical trial operations?

Group Discussion

The TransCelerate position paper on the RBM methodology defines three dimensions that should be evaluated in respect to the effectiveness of implementing the RBM model: quality, timeliness/cycle time (of data collection and issue resolution), and efficiency of trial operations.

It is critical to know ahead of time whether we plan to compare our RBM metrics to historical data or simultaneously to an ongoing “control” program or study to measure efficiency, quality and cycle time changes.

These dimensions should not be evaluated in isolation or used individually to draw conclusions. They should be used collectively to make business decisions about RBM. Sponsors may choose to use and evaluate metrics on an ongoing basis during the study or after the closure of a study for a higher level of evaluation at the program level. Can you identify at least one metric within each dimension to evaluate the effectiveness of the RBM methodology on clinical trial operations? Let’s start by just looking at the Quality dimension.
Metrics to Measure Impact

**IMPORTANT NOTE**

Answers for each dimension is shown the following slides.

**Facilitating the Activity**

Allow 15 minutes for this activity

**Classroom Workshop Participants (face-to-face)**

Ask participants to work within their table teams and flipchart their responses to identify one to three metrics within each dimension.

**Webinar Workshop Participants (online)**

Open a new whiteboard online with three sections (one for each of the three dimensions on this slide) and ask participants to write in responses for each dimension.
In the Quality dimension, the TransCelerate position paper suggests these possible metrics:

- Number and classification of major/critical audit/inspections findings per audited site
- Number of significant protocol deviations per site
- Number of unreported, confirmed Serious Adverse Events (SAEs)

Improvements or reductions in these measurements, as compared to a study that was conducted through a non-RBM model, would indicate the RBM methodology positively impacted the level of Quality in the trial.
Metrics to Measure Impact

TransCelerate Suggestions for Evaluating RBM – Timeliness/Cycle Time

Dimensions to Assess

- Quality
- Timeliness/Cycle Time
- Efficiency

• Average number of days from data entry to monitoring
• Median number of days from visit to data entry
• Median number of days from query open to close

Discussion Debrief – Timeliness / Cycle Time

In the Timeliness/Cycle Time dimension, the TransCelerate position paper suggests these possible metrics:
  • Average number of days from data entry to initial monitoring
  • Median number of days from visit to CRF data entry
  • Median number of days from query open to close

Improvements or reductions in these measurements, as compared to a study that was conducted through a non-RBM model, would indicate the RBM methodology improved the Timeliness/Cycle Time dimension. In other words, the RBM model allowed us to reduce the cycle times for data entry, monitoring, and query resolution.
Metrics to Measure Impact

TransCelerate Suggestions for Evaluating RBM - Efficiency

Dimensions to Assess

- Quality
- Timeliness/Cycle Time
- Efficiency

- Average monitoring (all types) cost per site
- Average interval between on-site monitoring visits per site
Discussion Debrief – Efficiency

In the Efficiency dimension, the TransCelerate position paper suggests these possible metrics:

• Average monitoring (all types) cost per site
• Average interval between On-site Monitoring visits per site

No one metric can be considered in isolation to assess impact of the RBM methodology. A holistic analysis of all metrics must be performed to gauge level of success.

Let’s give you an opportunity to practice the use of metrics in a quick challenge.
Metrics to Measure Impact

Slide 27

Challenge Yourself

Imagine that your organization has completed a study in which the RBM model was piloted. Please review the graphs on the next three slides which provide a comparison of metrics from the pilot RBM protocol and a similar protocol using your company’s traditional monitoring approach.

Challenge Yourself Activity

Imagine that the RBM methodology has been piloted in your organization on a study which has just been completed.

Three metrics –
1. average number of significant protocol deviations per site,
2. median number of days between queries being opened and closed, and
3. the average interval between on-site monitoring visits

have been gathered for both the RBM pilot study and a similar study using your company’s traditional monitoring approach.

IMPORTANT NOTE

Answers for all three metrics are shown after the three questions on a separate slide with debrief notes.
Metrics to Measure Impact

Facilitating the Activity

**Classroom or Webinar Workshop Participants (face-to-face or online)**

Share each of the following graphical slides to the class. After each slide, allow participants a moment to jot down their response to the question of impact on the metric being measured (Positive, Neutral or Negative) on a piece of paper or post-it note.

Debrief all answers at once.

**Challenge Yourself – Quality Metric**

What was the impact on Quality in the RBM pilot?

- **Positive**
- **Neutral**
- **Negative**

![Bar chart showing impact of RBM vs. Traditional](chart.png)

- RBM
- Traditional

Average Number of Significant Protocol Deviations Per Site
Metrics to Measure Impact

Key Notes / Information to Share

The average number of significant protocol deviations per site was approximately 15% lower in the study using the RBM methodology (3.6/site in RBM vs. 4.3/site in Traditional)

Write down your assessment, based on the metrics provided, what was the impact on Quality in the RBM pilot – positive, neutral, or negative?

Slide 29

Challenge Yourself – Timeliness/Cycle Time Metric

What was the impact on Timeliness/Cycle Time in the RBM pilot?

Positive  Neutral  Negative

![Graph showing median number of days between query open and close dates for RBM and Traditional methods.]

Key Notes / Information to Share

The graph on this slide represents this hypothetical data:
The median number of days between query open and close dates was approximately 20% higher in the study using the RBM methodology (14 days in RBM vs. 12 days in Traditional).

Write down your assessment, based on the metrics provided, what was the impact on Timeliness/Cycle Time in the RBM pilot – positive, neutral, or negative?
IMPORTANT NOTE

The major questions to be asked now are – Why did the query resolution take longer in the RBM pilot? What needs to be done to improve the situation? Possible actions include the following:

- Investigating whether off-site monitoring activities to address query resolution were being performed as planned in the RBM pilot
- Evaluating the clarity of site communications regarding expectations for query resolution in the RBM pilot
- Considering differences between the studies/investigative sites in the two protocols being compared such as query process, volume of queries, investigative site experience, monitor experience, country location of site, etc.

Challenge Yourself – Efficiency Metric

What was the impact on Efficiency in the RBM pilot?

Positive  Neutral  Negative

![Bar chart showing impact of Efficiency on RBM and Traditional methods](chart.png)
Metrics to Measure Impact

Key Notes / Information to Share

The graph on this slide represents this hypothetical data:
The average interval between on-site monitoring visits per site was slightly extended (by 0.1 weeks) using the RBM methodology (5.1 weeks for RBM vs. 5.2 weeks for Traditional).

Write down your assessment, based on the metrics provided, what was the impact on Efficiency in the RBM pilot – positive, neutral, or negative?

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Challenge Yourself – Answer Key

- What was the impact on Quality in the RBM pilot?
  - Positive  Neutral  Negative

- What was the impact on Timeliness/Cycle Time in the RBM pilot?
  - Positive  Neutral  Negative

- What was the impact on Efficiency in the RBM pilot?
  - Positive  Neutral  Negative
Metrics to Measure Impact

Challenge Yourself Activity Debrief

Quality – Positive because the average number of significant protocol deviations per investigative site was lower in the RBM pilot.

Timeliness/Cycle Time – Negative because the median number of days from query open to close increased in the RBM pilot.

Efficiency – Neutral because the reduction in the average interval between on-site visits per investigative site is only 0.1 weeks (probably not statistically significant).

The major questions to be asked now are – Why did the query resolution take longer in the RBM pilot? What needs to be done to improve the situation? Possible actions include the following:

• Investigating whether off-site monitoring activities to address query resolution were being performed as planned in the RBM pilot
• Evaluating the clarity of investigative site communications regarding expectations for query resolution in the RBM pilot
• Considering differences between the studies/investigative sites in the two protocols being compared such as query process, volume of queries, investigative site experience, monitor experience, etc.

IMPORTANT NOTE

You may want / need to return back to the graph slides to review any questions or key points during discussion.
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Effective Transition Techniques

Introduction

Now that we’ve reviewed how we can inform and prepare investigative sites for a shift to the RBM model and how we can measure the impact of the RBM methodology, let’s look at what is needed to effectively transition a study or certain investigative sites to Risk-Based Monitoring.
Effective Transition Techniques

IMPORTANT NOTE

The image is meant to provide a reminder and overview of the key elements in the TransCelerate RBM. Introduction of each numbered step can be general as noted in the speaker text or can be skipped depending upon learners’ familiarity with the TransCelerate methodology.

Make the following key points:

- One of the key central monitoring activities is the implementation of those Risk Indicators and Thresholds. A companion guide has been developed by TransCelerate to provide guidance on Risk Indicators and Thresholds.

- The entire process is dependent on QbD starting with the protocol and case report form development as an important foundation with an impact on quality and efficient monitoring.
Effective Transition Techniques

Process and Associated Tools

The image on the screen shows an overview of TransCelerate’s methodology. The methodology proceeds in a stepwise fashion; at each step, sponsors should document the decisions made, rationales, and appropriate plans.

1. As you can see, RBM Methodology begins with the completion of risk assessments (labeled with the number one). The RACT (Risk Assessment Categorization Tool) is a tool which can be used for risk assessment. This tool was reviewed in module 3.
2. Step two involves defining Critical Variables which includes Critical Data and Processes, first at the program level, and then in further detailed evaluation at the protocol or trial level.
3. The third step is related to the development of the Integrated Quality and Risk Management Plan, also called the IQRMP. In the RBM methodology, this is an overarching plan that connects all of the various quality and risk management strategies. The IQRMP may include the Medical Monitoring Plan, Data Plan, Training Plan, Monitoring Plan, Safety Plan, and Statistical Analysis Plan, just to name a few. The Monitoring Plan (MP) describes central monitoring, off-site and on-site monitoring activities. The development of the monitoring plan includes the identification of Risk Indicators and Thresholds.
4. The final or fourth step involves the execution of the predetermined monitoring activities.
Effective Transition Techniques

Slide 34

**Discussion Point**

Can a study be transitioned into RBM if it has already started and is being monitored with a different approach? If yes, where in the process would you start?

**Group Discussion**

Facilitate a group discussion about transitioning studies into RBM after it is already started and being monitored with a different approach.

**Facilitating the Activity**

Allow 5 minutes for this activity

**Classroom OR Webinar Workshop Participants (face-to-face OR online)**

Ask participants to offer their thoughts as a large group (raising their hands OR for face-to-face participants you could have discussions at the tables).

Document responses and ideas on a physical flipchart or virtual whiteboard.
Effective Transition Techniques

Discussion Debrief

Key points:
Yes, this kind of transitioning is possible. However, a transition of this type should be carefully considered from a quality risk management approach. The team would need to identify the risks involved in transitioning to RBM and plan to prevent or minimize those risks. Therefore, a transition of this kind would start in the process with step 1 – risk assessment. The cross-functional team would need to perform an additional risk assessment on the transition itself as well as the customary risk assessments at the program and protocol levels. The remainder of the process would follow just as one would if starting a study in the RBM methodology with the exception that instead of writing various functional risk mitigation plans, we would be revising those that currently exist.
Effective Transition Techniques

Transition Scenarios for Ongoing Studies

- Sites
  - All Sites
  - Selection of Sites
- Stage
  - Prior to Study Start
  - Ongoing study
    - During enrollment
    - After enrollment is complete

Direct participants to the Participant Workbook
Effective Transition Techniques

Transition Scenarios for Ongoing Studies

When we speak of “transitioning”, we mean changing an existing monitoring approach to the RBM methodology, as opposed to starting a program or protocol using RBM concepts.

There are many options for transitioning studies to RBM either for different sets of sites or at different stages of the study.

All investigative sites within an ongoing study may be transitioned to RBM. There may also be situations where certain investigative sites within an ongoing study may be transitioned to the RBM model while the remaining investigative sites on the study are monitored according to the standard approach.

For example, a subset of sites may be chosen to serve as the “RBM pilot” within a study that is being monitored through a standard approach.

If the RBM methodology is not in place prior to study start, ongoing studies may be transitioned to RBM either during enrollment or after enrollment is complete.

Let’s review a few actual transition scenarios to get a better feel for applying techniques to effectively transition studies and/or sites including:

1. ongoing study (all investigative sites) after enrollment completed
2. ongoing study (all investigative sites) during enrollment and
3. a sample of investigative sites for an ongoing study
Scenario 1 – Ongoing Study, After Enrollment

- Enrollment complete at all sites
- Subjects in 2 year follow-up
- Senior management requests that the monitoring approach be transitioned to the RBM methodology for all sites

**How can we most effectively manage the transition?**

Group Discussion

Facilitate a group discussion about managing the transition for this scenario.

Facilitating the Activity

Allow 5 minutes for this activity

**IMPORTANT NOTE**

Answer key for this and next scenarios is provided on slide 39 after all three scenarios are completed.
Effective Transition Techniques

Classroom OR Webinar Workshop Participants (face-to-face OR online)

Ask participants to offer their thoughts as a large group (raising their hands OR for face-to-face participants you could have discussions at the tables).

Document responses and ideas on a physical flipchart or virtual whiteboard.

Group Discussion Debrief

Hints for things to consider:

- Where in the overall process of the RBM methodology does the team need to start?
- What existing documents may be affected and require revision?
- What communication and/or training need to occur?
Effective Transition Techniques

Slide 37

Scenario 2 – Ongoing Study, During Enrollment

- Large, late phase 3 study - ongoing with 80% of enrollment complete when the product is approved
- Current study is amended to include a “roll-over” option for completing subjects
- Senior management requests transition to the RBM methodology for the “roll-over” phase of the study

How can we most effectively manage the transition?

Challenge

Group Discussion

Facilitate a group discussion about managing the transition for this scenario.

Facilitating the Activity

Allow 5 minutes for this activity

IMPORTANT NOTE

Answer key for this and next scenarios is provided on slide 39 after all three scenarios are completed.
Effective Transition Techniques

Classroom OR Webinar Workshop Participants (face-to-face OR online)

Ask participants to offer their thoughts as a large group (raising their hands OR for face-to-face participants you could have discussions at the tables).

Document responses and ideas on a physical flipchart or virtual whiteboard.

Group Discussion Debrief

Hints for things to consider:

- Where in the overall process of the RBM methodology does the team need to start?
- What existing documents may be affected and require revision?
- What communication and/or training need to occur?
Effective Transition Techniques

Scenario 3 – Specific Sites, Ongoing Study

- Ongoing study in open enrollment
- Senior management requests that a randomly selected sample of sites be selected to transition to RBM methodology
- Results of this “pilot” will be used to decide future monitoring approach for the company

How can we most effectively manage the transition?

Group Discussion

Facilitate a group discussion about managing the transition for this scenario.

Facilitating the Activity

Allow 5 minutes for this activity

IMPORTANT NOTE

Answer key for this and next scenarios is provided on slide 39 after all three scenarios are completed.
Effective Transition Techniques

Classroom OR Webinar Workshop Participants (face-to-face OR online)

Ask participants to offer their thoughts as a large group (raising their hands OR for face-to-face participants you could have discussions at the tables).

Document responses and ideas on a physical flipchart or virtual whiteboard.

Group Discussion Debrief

Hints for things to consider:

- Where in the overall process of the RBM methodology does the team need to start?
- What existing documents may be affected and require revision?
- What communication and/or training need to occur?
Effective Transition Techniques

Transition Scenarios - Answer Key

- Assess risks (complete the RACT)
  - Program level and protocol level
  - Evaluate technological capacity and systems — determine central and off-site monitoring capabilities
- Identify Critical Variables, Risk Indicators and Thresholds
- Revise Monitoring Plan and other functional risk mitigation plans accordingly
- Determine impact to budgets and timelines
- Negotiate revisions to contracts with vendors (if necessary)
- Train all associated personnel
- Communicate to and prepare sites
- Establish metrics for quality, timeliness/cycle time, and efficiency

IMPORTANT NOTE

Answer Key may not be all-inclusive.

Emphasis that any transition, whether of an entire study or selected sites, during or after enrollment, must start with the first step of the RBM methodology - Risk Assessment through completion of the RACT.

The remaining steps of the methodology are then applied through revision of functional risk mitigation plans, establishing the monitoring approach and activities, communicating and training all associated personnel, including sites, and preparing for metrics to evaluate the effectiveness of the RBM implementation.
Effective Transition Techniques

Techniques for Transition - Summary

- Follow RBM methodology process
- Revise risk mitigation plans accordingly
- Consider technology, budget, and timeline factors
- Communicate (internally and externally)
- Identify and address training gaps
- Plan for lessons learned and metrics to evaluate

Summary – Techniques for Transitions

In summary, these are the common techniques to promote the successful transition of studies and/or sites to the RBM methodology.

- It is recommended that we do not skip any of the steps in the RBM methodology process.
- The risk assessment, identification of Critical Variables, Risk Indicators and Thresholds leads into the revisions of applicable risk mitigation plans.
- An important consideration is how and whether our technology can support the RBM model fully. In most transitions, there may be impacts to budgets and timelines that need to be evaluated.
- Communication of the plan, both internally and externally, is critical. We will also need to identify training gaps, both internally and externally, and address those needs.
- Finally, we should consider how we will evaluate the impact of the transition and plan for lessons learned.
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Challenges with RBM Implementation

Introduction

In closing this module, let’s discuss the possible challenges that may be met when implementing Risk-Based Monitoring.
Challenges with RBM Implementation

Slide 42

Challenges with Change

- Cultural – We’ve always done it this way
- Systems – The systems we have require that we do it this way

- Fear of the unknown
- Likes things the way they are
- Confused about the change
- Too busy
- Fear of failure
- Doesn’t fit with SOPs
- Perceives change as more work

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Direct participants to the Participant Workbook
Challenges with RBM Implementation

Challenges with Change

Whenever we encounter a change in the industry or with an internal process, there may be challenges and possibly resistance.

Challenges with any change can be based in the culture of an organization/company or from cultural differences in the areas where we conduct our trials. Other challenges can arise from perceived limitations of the systems we use. Individuals may defend the current process or raise an objection to the new methodology by saying it will require new systems or technology.

Example 1: Different country cultures pose a significant challenge for implementing RBM.
Example 2: Study team agrees with RBM concepts/principles but do not think it can be implemented or do not want it to be applied to their study.

You may hear statements like

- “That’s not the way we do things here.”
- “We’ve always done it this way.”
- “The system won’t work that way.”
- “What if this leads to an inspection finding?”

The best way to meet challenges with any new idea or methodology is to be prepared and to understand the reasons or motivation behind the challenges.

Some of the reasons for resistance are stated on the slide - it may be that some individuals understand the upcoming change but don’t agree with it; there may be some fear of the unknown; or team members may even be concerned about the change generating more work for everyone.
Challenges with RBM Implementation

Areas of Implementation Challenges for RBM

- Global
- Regional
- Company
- Investigator

Areas of Implementation Challenges

The challenges encountered in implementing the RBM methodology exist in four general areas:

- Challenges encountered when working with global teams and/or investigative sites
- Challenges that exist due to differences in specific regions or countries
- Challenges arising within our own companies or organizations which may be related to
  - Individual personnel who are resistant to change
  - Implementation of the RBM model across different functional areas within the company
- Challenges encountered due to specific characteristics of investigative sites or institutions

Let’s look at each of these individually.
Global Challenges

- Regulatory authority perspective
- Language considerations
- Cultural

In the global arena, we may face challenges as to whether the regulatory authority(ies) in the areas where we work are in support of the concept of applying risk-based approaches to monitoring.

This uncertainty could result in global team members and/or investigative sites resisting the implementation of RBM.

There are language challenges that must be managed. The TransCelerate RBM methodology includes specific terminology, principles, and concepts that will need to be translated correctly into local languages to ensure full comprehension and success.

Challenges may arise due to a variety of cultural differences (e.g. roles and responsibilities or different staffing/personnel models).
Challenges with RBM Implementation

Regional Challenges

• Acceptance by ethics committees
• Availability and use of technology
• Research infrastructure
Challenges with RBM Implementation

Regional Challenges

In addition to global challenges faced when we work internationally, there may be some regional or country-specific challenges as well.

In some regions, ethics committees will request information on how the sponsor plans to monitor the study, to obtain assurance that subject safety will be protected. These ethics committees may not be familiar with or readily accept the RBM methodology.

As greater reliance on technology is fundamental to the success of RBM, any technological challenges in certain regions can be particularly problematic. Hardware (laptops and/or workstations) must not only be available but personnel must be comfortable with the technology and appropriately trained on its use.

Some regions have a basic research infrastructure in which the investigator may be the only individual working on the trial. There may be no study coordinators or research assistants; the investigator conducts all study visits, prepares all source documentation and completes the case report forms. Think about ways to implement quality assurance methods in this type of environment.

Some regions and cultures have a defined hierarchy in professional relationships that result in physicians or other advanced degree holders being hired as Clinical Research Associates/Monitors. This allows more peer-to-peer partnerships between these personnel and investigators. In the RBM model, investigators will be interacting with many other sponsor personnel who are likely not physicians.
Challenges with RBM Implementation

Slide 46

Discussion Point

Can you name specific challenges that you would anticipate with your company and/or organization?

Direct participants to the Participant Workbook

Group Discussion

Facilitate a group discussion about challenges you anticipate with your company and/or organization in implementing RBM.

Facilitating the Activity

Allow 5 minutes for this activity

Classroom OR Webinar Workshop Participants (face-to-face OR online)

Ask participants to offer their thoughts as a large group (raising their hands OR for face-to-face participants you could have discussions at the tables).

Document responses and ideas on a physical flipchart or virtual whiteboard.
Challenges with RBM Implementation

Company Challenges

- SOPs may be complex or not easily changed
- Resourcing
- Change management
- Technology and systems
- Strategic partnerships

Discussion Debrief

- SOPs and work processes will need to be revised; there may be challenges if they are complex or not easily changed.
- Do we have sufficient resources internally? Will job descriptions need to be revised? Clarification in roles and responsibilities is critical.
- Does our culture support change? What resources are available for change management?
- Technology and systems (including those of outside vendors like Data Management, Interactive Voice Response Systems (IVRS), Interactive Response Technology (IRT), electronic patient reported outcomes (ePRO), central labs, etc.)
- Strategic partnerships - do sponsor and partner view RBM the same? What are the partner’s RBM capabilities and experience?
Challenges with RBM Implementation

Slide 48

Investigator Challenges

Some considerations may include:

- Institutional SOPs
- Resourcing
- Technology
- Contract/budgeting

Can you think of any additional challenges that may be encountered with specific sites or investigators?

Group Discussion

Facilitate a group discussion about any additional challenges that may be encountered with specific sites or investigators.

Facilitating the Activity

Allow 5 minutes for this activity.

Classroom OR Webinar Workshop Participants (face-to-face OR online)

Ask participants to offer their thoughts as a large group (raising their hands OR for face-to-face participants you could have discussions at the tables).

Document responses and ideas on a physical flipchart or virtual whiteboard.
Challenges with RBM Implementation

Discussion Debrief

Key Points

The investigators and institutions with whom we work may have various limitations that can pose challenges to RBM implementation. For example,

- Institutional SOPs may be complex and/or not readily changed. Therefore, it might be difficult for them to implement internal quality assurance or issues management (root cause analysis, corrective and preventive action plans) policies and procedures.
- There may be problems obtaining sufficient personnel to meet expectations for timely data entry, query responsiveness, quality assurance, etc.
- As mentioned previously, technological resources must be available and personnel must be comfortable with and trained on its use.
- Contracts and/or budgets may need to be revised in the RBM methodology such as to include data entry expectations, identification of how payments are triggered if not using Source Data Verification any longer, sites may request compensation for internal quality assurance, etc. This process can lead to time delays and/or budgetary challenges.
Challenges with RBM Implementation

Group Challenge

- Global study using new RBM methodology which is becoming the standard for your company
- Central/off-site monitoring will occur at headquarters in California
- 40% of sites are located in India; remainder in North America
- Electronic Data Capture will be used

As a group, identify as many potential challenges as possible that may be encountered with RBM implementation for this study.

Group Discussion

Ask a participant to read the bullet points that summarize the scenario information. Facilitate a discussion to brainstorm as many potential challenges as possible that may be encountered with RBM implementation on this study.

Facilitating the Activity

Allow 5 minutes for this activity.

IMPORTANT NOTE

Answer key for this and next scenarios is provided on the next slide.

*Classroom OR Webinar Workshop Participants (face-to-face OR online)*

Ask participants to offer their thoughts as a large group (raising their hands OR for face-to-face participants you could have discussions at the tables).

Document responses and ideas on a physical flipchart or virtual whiteboard.
Challenges with RBM Implementation

Slide 50

Group Challenge – Answer Key

- Sites in India:
  - Regulatory authority perspective and ethics committee acceptance
  - Language considerations
  - Research infrastructure and resourcing
- Study overall:
  - Resourcing
  - Contract/budget
Challenges with RBM Implementation

Group Discussion Debrief

The sites in India may present many of the global and regional challenges we reviewed earlier:

• Will the regulatory authority support RBM? Do ethics committees there review monitoring methods? If yes, will they accept RBM?

• Although English is widely spoken in India, there may be some language challenges as RBM terminology may not be familiar to those in India

• Research infrastructure and resourcing – is there sufficient staff and infrastructure to meet timely data entry and resolution expectations?

The study overall may face some challenges as follows:

• Resourcing – are staff available to perform central/off-site monitoring activities in real-time across numerous time zones? Who will discuss issues and findings with investigators and when? Middle of the night teleconferences?

• Contract/budget – if hardware needs to be supplied, study budgets will increase. If sites need to hire personnel to meet timely data entry expectations, they may request budgetary support.
Challenges with RBM Implementation

Time For Reflection

- What are the challenges with RBM implementation facing your specific role?
- Can you identify any tools, systems, or strategies to help manage these challenges?

Reflection

Now that we have concluded our comprehensive discussion of the implementation of the Risk-Based Monitoring methodology, we’d like to give you the opportunity to reflect on specific challenges that might affect your role in the organization.

Let’s not get stuck on the challenges, however. Try to also identify any possible tools, systems, or strategies that currently exist or could be developed to manage these challenges.

IMPORTANT NOTE

This provides an opportunity for each participant to spend a few minutes thinking about how their individual role may be affected or challenged by RBM implementation. Participants should be encouraged to identify any possible tools, systems, or strategies that currently exist or could be developed to manage these challenges.

A suggested list of solutions appears on the next slide.
Challenges with RBM Implementation

Meeting Our Challenges

- Risk Indicators/Threshold reminders on new or existing tools
- Redesign Source data verification (SDV) tracker to reflect RBM
- Create a project calendar displaying schedule of monitoring activities performed by various functional areas
- Enhance existing reporting systems to provide color-coded visuals for Thresholds
- Develop RBM-specific training for sites on internal quality assurance
- Develop Advanced EDC training
- Provide scenario-based training for monitoring personnel in regards to evaluating Thresholds and responding to issues
Challenges with RBM Implementation

Meeting our Challenges

A suggested list of solutions appears on this slide. Of course, each organization will define and develop its own tools, systems, and strategies to streamline and facilitate the implementation of the RBM model.

• Develop or revise existing tools or worksheets to adapt to RBM methodology – for example, add Risk Indicators/Threshold reminders on existing tools; redesign SDV tracker for Clinical Research Associate use
• Establish a communication plan or methodology for sharing monitoring activity across functional areas – for example, a calendar to display frequency of reports pulled/reviewed across various functional plans or areas
• Enhance existing dashboard or reporting systems to provide color-coded visuals for Thresholds
• Consider developing RBM-specific training for sites in regards to developing their own internal quality assurance functions/activities
• Develop Advanced EDC training to cover topics such as trending review and generating reports and listings
• Provide RBM-specific training for Clinical Research Associates at study kick-off meetings with study-specific scenarios to practice application of monitoring plan content, Risk Indicators and Thresholds, and responding to issues
Module 5: Summary

Slide 53

Module 5 Summary

Successful transitioning to the RBM methodology requires:

- Information to be provided to sites to help them understand and manage change
- Strategies to measure the impact of RBM
- Techniques to ensure efficiency
- Understanding and preparing for potential challenges

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Direct participants to the Participant Workbook

Summary of Module 5

Review the module summary key points on the slide.
Module 5: Summary

Questions

Questions