



AR10 RBM Beyond the Mandate: The Importance and Impacts of Risk-Based Monitoring Today

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RBQM

In August 2013 the FDA stated its wish to support RBM stating that a mix of centralized and on-site monitoring practices would be good for the patient protection and study integrity.

Transcelerate defines RBM as an adaptive process approach to clinical trial monitoring that direct monitoring focus and activities to the evolving areas of greatest need which have the most potential to impact patient safety and data quality”

Who is the room is performing RBQM in your organization?

Why RBQM?

Understanding and monitoring risks within the clinical trial is not just an ICH mandate, but also has the potential to improve data quality, time to market and most importantly patient safety.

The industry is seeing an increasing amount of data sources for a clinical studies, from 5 - 7 to more than 15 per study, with more and more external data as we move to the concept of decentralized studies.

How many data sources are you dealing with in your studies?

Why RBQM?

Some of the major challenges in a clinical trial conduct include

- delays in data entry,
- misconduct at the site,
- degradation of data quality We need to document and monitoring against these RISK's.

This means we need to have access to various sources in one holistic location to be able to assess all the possible risks.

In the example of delays in data entry, having access to the audit trails for EDC systems allows us to monitor and report when these risks materialize within the study.

RACT (Risk Assessment Categorization Tool)

Risk Based Management is still evolving through the use of data, in order to mitigate these risks.

Planning and documenting these risks and associated mitigation actions within the RACT helps us

- plan,
- monitor and
- take action in a timely manner,

when or if these risks occur during the conduct of the study.

The RBM to RBQM Transformation

RBM: (Risk Based Monitoring)

- Looking for risk everywhere
- Actioning all defects
- Managing all risks the same



- 100% SDV
- Addresses risk when they occur

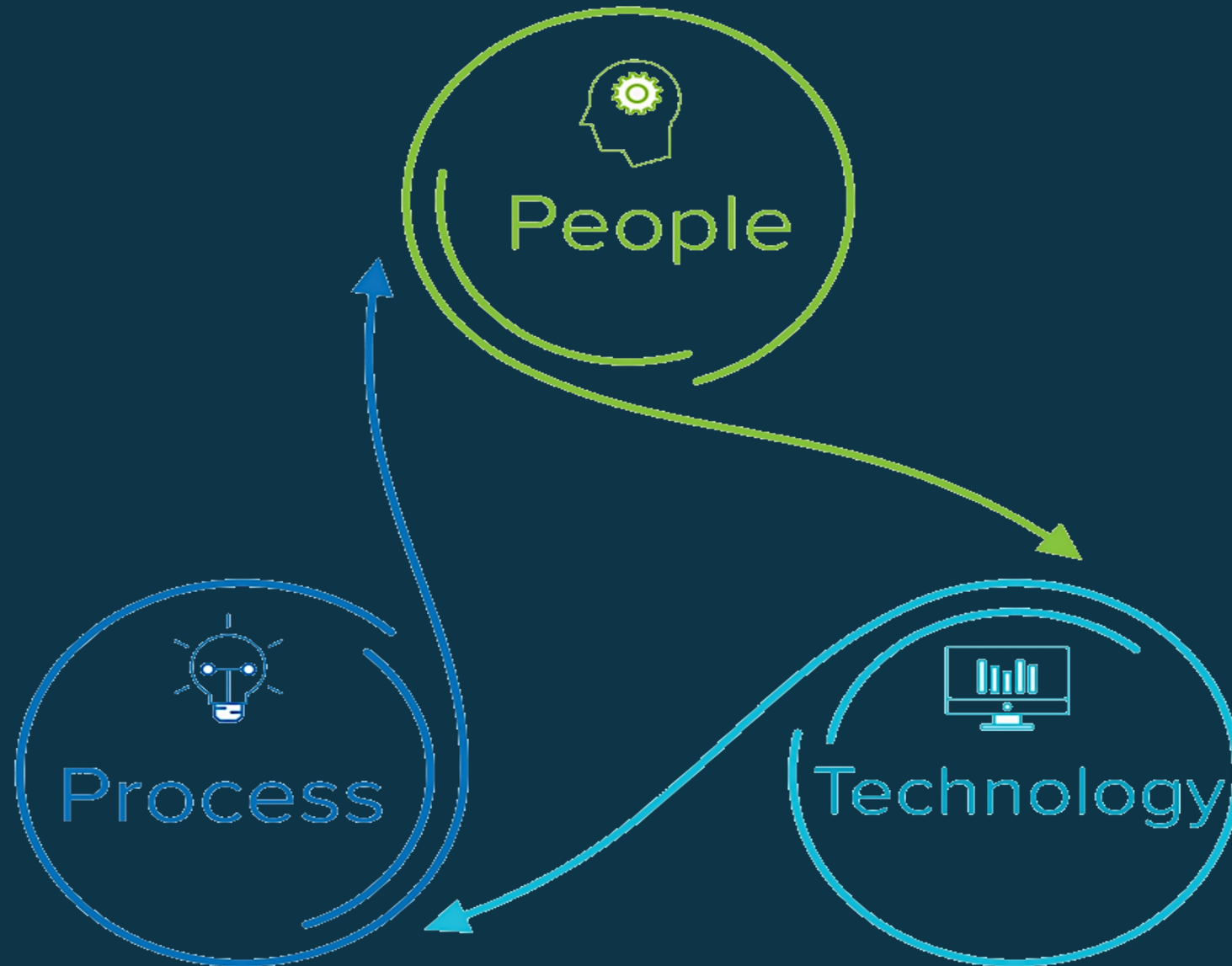
RBQM: (Risk Based Quality Management)

- Defining risks early
- Accepting some risk
- Customizes monitoring plans
- Past trials should inform future trials

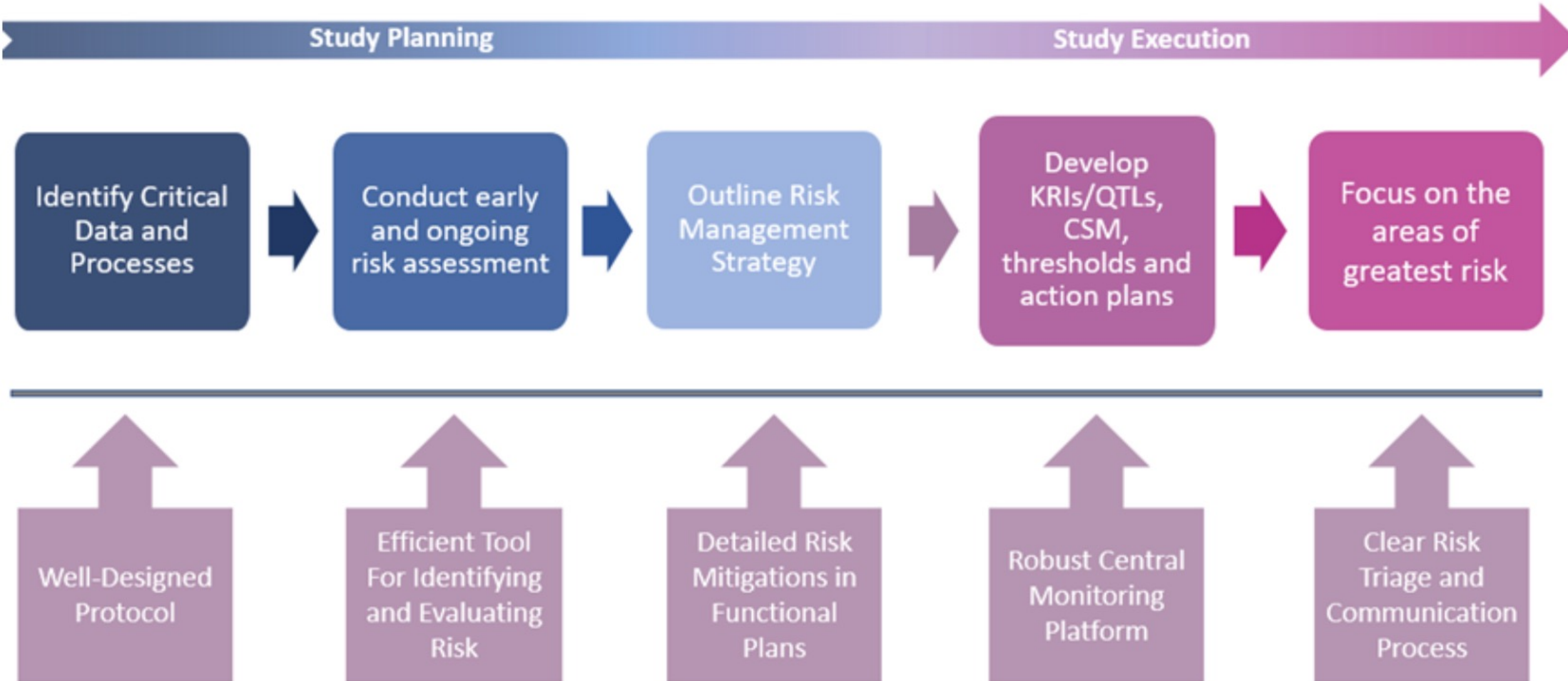


- Risk Assessment
- Risk Categorization
- Defining all risk
- Creating separate action plans for each risk

RBQM Process



RBQM Process



RBQM People

Developing the Risk Assessment and Categorization Tool (RACT), the Key Risk Indicators (KRIs), thresholds and the mitigation actions before protocol finalization is a team activity

The Centralized Monitor (CM) is a key role in the process

How many of you have the role of CM in your organizations?

Do we really need a dedicated CM for all studies?

Central Monitor Function

- Review output of the RBQM system to identify site performance issues on a regular, pre-agreed frequency from study start up to close-out.
- Early identification of site outliers, trends, signals and risk occurring during study conduct and responsible for identification of risk using pre-specified risk indicators agreed with Sponsor.
- Timely escalation of risk/issue(s) to relevant stakeholders (e.g., study manager, on-site monitors/CRAs) and tracking of risk/issue(s) until resolution.

Central Monitor Function

- Checks whether a finding is
 - a single event or ongoing (e.g., low data entry due to PI vacation),
 - determining if there is a non-issue,
 - or if the issue has already been resolved,
 - or if further investigation is needed with escalation and immediate mitigation action.
- Reviews site performance and makes recommendations to clinical team for timely corrective actions (e.g., Remote Call or Triggered Onsite/Remote MV).
- Communicates effectively with the project team and attends regular team meetings, client meetings, as per the project specific needs and for tracking/controlling of risk/issue(s).

Technology

We need to

- Plan in the form of the RACT
- Monitor to that plan, adjusting as appropriate during the study conduct
- Document any actions and communicate with the team

Who is using an RBQM tool?

In Conclusion

- RBQM is not new
- Timely and centralized data is needed to facilitate the monitoring
- Plan should be created before study start and updating appropriately throughout study conduct
- Agree who will monitoring the risks – maybe a dedicated CM
- Study team must be involved in defining risks, mitigation actions and review of any findings

PROCESS

PEOPLE

TECHNOLOGY

Thank You!

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