Risk Based Monitoring

Develop model guidelines for targeted, risk-based clinical trial monitoring, ultimately aiming to improve data quality and patient safety.

Value for Stakeholders

• **Earlier detection** of issues, with a greater focus on resolution and prevention of issue recurrence
  - “[RBM] has allowed us to improve patient safety and data integrity.” – Sponsor Company

• **Reduction in efforts** expended on low-value activities through centralization and data analysis

• **Cost reductions** through more focused centralized monitoring activities and targeted onsite monitoring
  - “On average the days between onsite visits increased 58% and there were 5 times more remote contacts with the sites, without any impact on the quality.” – Sponsor Company

• **Greater compliance** with Good Clinical Practice (GCP) and relevant regulatory requirements

• **A more collaborative** cross functional team approach – the coordination of monitors, data managers, statisticians, medical monitors, and site staff
  - “[RBM] enabled strong cross-functional and geographical collaboration among medical and safety staff. This improvement spills over to trial management and site monitoring staff.” – Sponsor Company

**Initiative Status**

*Last Update: September 2018*

- Explore
- Design
- Deliver
- **Maintain**

**Deliverables:**

All deliverables are updated on a regular basis and are available for public use on the TransCelerate website, including the following:

- ✓ Risk Assessment Categorization Tool (RACT) (Published 2014)
- ✓ Informational Materials (Published 2014)
- ✓ Risk Indicator Library (Published 2015)

**Focus Today:**

- Seek to **continuously improve methodology** through the sharing of qualitative and quantitative lessons learned.
- Drive **awareness of concepts and realized value** across stakeholders to enable adoption.
- Collect **examples of successful implementation** that can demonstrate solution value.
- **Monitor** landscape and potential events that could impact developed solutions.
- **Develop RBM Metrics Best Practices Adoption Story and Guidance.** To be completed by Q4 2018.