

Risk-based monitoring



Why adopt risk-based monitoring (RBM)?

Historically, life sciences clinical trial teams were pressed to visit trial sites according to a rigid site monitoring plan that requires equal attention be given to each site, regardless of need. This industry-standard, resource-intensive approach greatly reduces productivity, relies almost exclusively on manual assessments and gives equal weight to all data points. This old school approach is being left behind due to the acknowledgement that clinical trial costs are steadily increasing, and there is a great need to gain more data value for each dollar spent while not putting subject safety and efficacy measurements at greater risk.

Regulatory authorities recently have expressed support for the application of a risk-based model, where monitoring is conducted proportionate to the risks associated with the study. Advancements in both statistical analysis and IT system support have provided opportunities to capitalize on the acceptance of a new approach. Through the use of technology enablers, data can be obtained to provide the necessary insight to identify which sites require a higher level of oversight and which do not—all while managing risk, maintaining quality and ensuring subject safety. This proactive approach enables CRAs/monitors to more readily identify issues and provides the bigger picture of potential risk.

Plugging in a system is not enough

As the excitement around RBM has increased, we have seen an explosion in the number of RBM solutions. This abundance in solutions has led too many companies into thinking that simply plugging a new tool into their eClinical landscape will allow them to realize all the benefits of RBM—if only that were the case. Your existing eClinical systems may already house the data that is necessary to start RBM, but adding the new solution to the mix needs to be part of a larger risk-based monitoring initiative. In order to maximize the value from your risk-based monitoring initiative, you need to focus on the four main pillars that support any successful initiative:

- Process/framework – Aligning activities and tasks to the desired business outcomes
- People – Ensuring that you have the right people performing the right activities
- Technology – Implementing systems that support your desired future state processes



CGI's clinical experts

Choosing a consulting partner who can help drive change in your organization is a difficult process. Our team of consultants come from a variety of backgrounds with the clinical domain in life sciences (sponsor and CRO clinical operations, sponsor IT teams, eClinical vendors, and consultancies) and have proven over and over again that our experience and expertise can directly contribute to successful client partnerships.

- Information – Integrating systems so that information is able to analyzed and acted upon.

CGI's RBM methodology

CGI brings the experience, domain expertise, and a track record of successful implementations to our client's projects. CGI has a unique combination of clinical domain expertise and technical experience that will ensure a successful outcome.

Visioning and planning

- Identify why change is needed
- Identify objectives and critical success factors

Existing risk planning assessment

- Analyze current state against strategy
- Complete risk assessment and contingency plan

Monitoring program development

- Develop program framework and trigger / alert parameters
- Verify system requirements, if applicable

Process and organizational change

- Conduct impact assessment and action plan
- Identify how to implement changes

Solution deployment and training

- Ensure implementation of changes
- Iterate – monitor, evaluate and optimize

About CGI

Insights you can act on

Founded in 1976, CGI is among the largest IT and business consulting services firms in the world.

We are insights-driven and outcomes-based to help accelerate returns on your investments. Across hundreds of locations worldwide, we provide comprehensive, scalable and sustainable IT and business consulting services that are informed globally and delivered locally.

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