

## **"Risk-based Monitoring: Industry Guidance on Adoption, Use and Outsourcing"**

**ISR Reports, 2013, 144 pages, \$3,260**

**Review by Norman M. Goldfarb**

"Risk-based Monitoring: Industry Guidance on Adoption, Use and Outsourcing" is a timely, insightful, and practical resource for risk-based monitoring (RBM), the hottest trend in clinical research.

Respondents indicated that RBM is risky, 72% from an operational and 77% from a regulatory standpoint. Nevertheless, RBM is gaining momentum in 96% of respondent companies, primarily to reduce cost, but also to save time, increase data quality, reduce risk, minimize site disturbance, increase patient safety, and improve site performance. On average, respondents reduce monitoring costs by 23%.

Respondents with RBM experience indicate that 23% of their sites are high-risk, compared to 37% for respondents without RBM experience, suggesting that RBM might reduce risk by driving appropriate site selection.

The top five triggers or risk indicators include:

- Data quality, errors and flags
- Adverse events and safety data
- Protocol compliance
- Site experience, quality and performance
- Patient targets, evaluation and compliance

The report includes substantial qualitative data, such as the following useful advice:

- Actually understand the methodology.
- Assume 20% of sites will produce 80% of quality issues.
- Assume not all sites will comply.
- Make sure monitors embrace the concept and explain it to the sites.
- The burden shifts from the CRAs to the data management group, so having a strong data management group will benefit a risk-based monitoring strategy.

The report includes 83 charts and figures, based on data collected from 78 respondents at pharma and biotech companies, 89% with RBM experience. It is organized in seven sections:

- RBM awareness and definition
- Study characteristics best fit for a RBM study
- Sponsor perception and use of RBM
- Data and technology
- Outsourcing environment
- Save money with RBM?
- Respondent demographics

The report is available at <http://www.isrreports.com>.

**Reviewer**

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