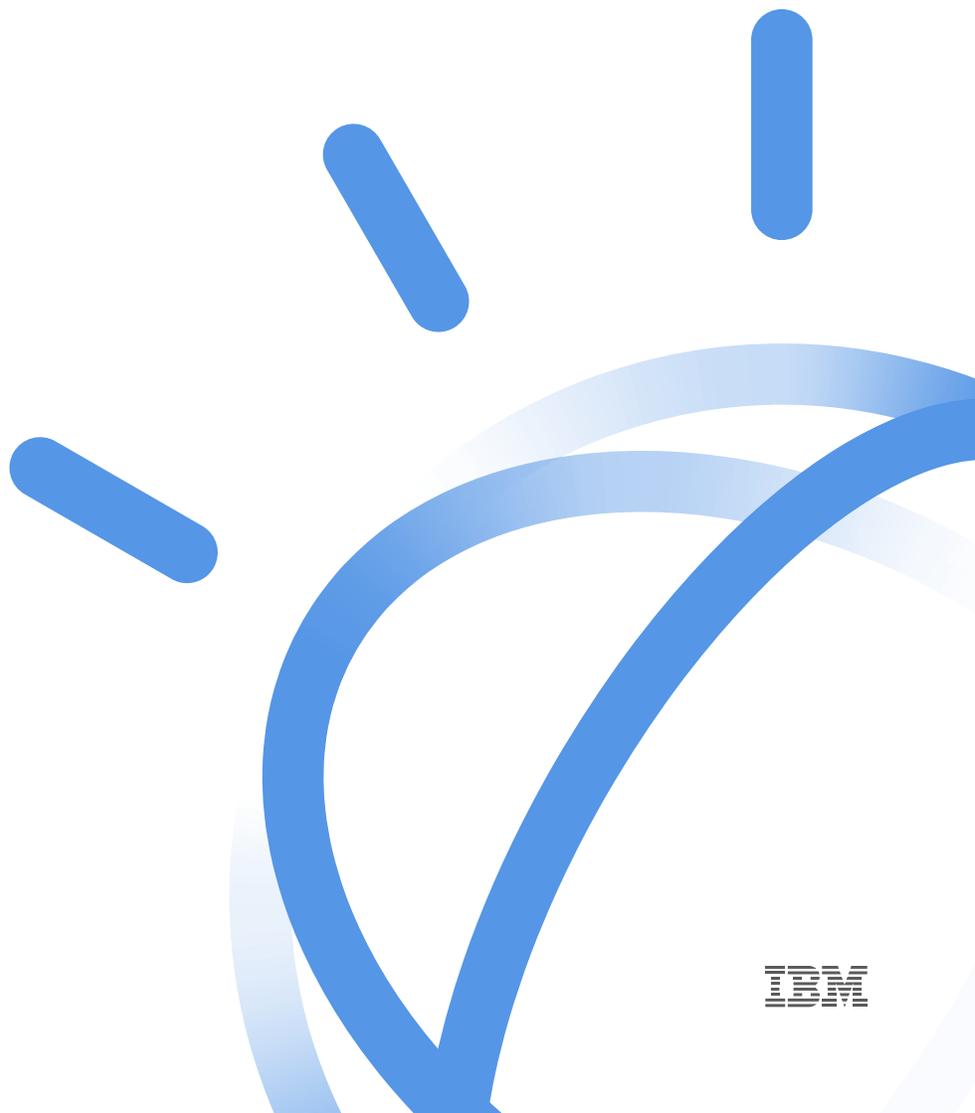


IBM Clinical Development Risk Based Monitoring

Improve overall study quality,
operations and economics



Key benefits

- A knowledge engine that uses machine learning and statistical algorithms to help predict, detect, analyze and manage risk
- Protocol-specific site scoring that helps you evaluate site performance and focus on those that pose the highest risk
- Customized alerts that notify you immediately of potential concerns so you can take appropriate action and make informed, evidence-based decisions

RBM delivers “cost savings up to 25 percent”³

Although only 1.1 percent of data are ever corrected as a result of Source Data Verification (SDV), the estimated cost of onsite monitoring accounts for up to 50 percent of every trial budget.^{1,2} Regulators, Sponsors and CROs are advocating a risk-based approach to address this problem and make trials safer, faster and more cost-efficient. And in late 2016, the risk-based approach will become part of Good Clinical Practice (GCP) with the expected approval of new ICH E6 guidelines.

The Watson Health and Remarque RBM integration

Watson Health™ has teamed with Remarque Systems to offer IBM® Clinical Development customers the most advanced Risk-Based Monitoring (RBM) capabilities available. This innovative integration of a purpose-built RBM application into a robust EDC platform is designed to allow seamless data exchange for end-to-end management in an RBM environment. A cloud-based, SaaS model, the IBM® Clinical Development Risk Based Monitoring/Remarque RBM solution can be quickly deployed, with no additional infrastructure required.

The Remarque RBM platform delivers near real-time data exchange, robust risk assessment tools along with role-based views and functions. So you can identify and address potential risks before they become problems and help improve overall study quality, operations and economics. You can also modify, add or update key risk indicators, triggers and thresholds at any point to reflect changing trial conditions. And with all trial data at your fingertips, the time from study end to results is faster than ever.

IBM Clinical Development is one of the only EDC platforms that offers this much power, flexibility and functionality to conduct RBM trials. And just like IBM Clinical Development, Remarque RBM is scalable, so it grows as you grow.

Robust RBM capabilities

Remarque RBM offers an intuitive, workflow-enabled, audit trail-supported environment comprising:

- **A knowledge engine** that uses machine learning and statistical algorithms to predict, detect, analyze and manage risk
- **Built-in TransCelerate Risk Assessment and Categorization Tool (RACT) or Risk Register** to assess and document risks
- **Protocol-specific site scoring** that helps you evaluate site performance and focus on those that pose the highest risk
- **Customized alerts** that notify you immediately of potential concerns so you can take appropriate action and make informed, evidence-based decisions
- **Robust workflow functionality** built into every role to convert findings into trackable actions
- **Interactive role-driven visualizations with drill-down capabilities** courtesy of a built-in Business Process Management engine
- **Signal-Driven SDV™** that recommends changes to SDV levels that you can change in IBM Clinical Development at the study, site or patient level.

- **System-agnostic data intake** to import data from virtually any source in any format need for a data warehouse
- **A Medical Monitor module** that allows the medical monitor to quickly identify and address potential safety concerns and anomalous data trends
- **Workflow packaging capabilities** that let you efficiently manage optimal mode (email, phone, and visit) and cadence of site contact

Put RBM benefits to work to help you



IBM Clinical Development and Remarket RBM: Stay ahead of the curve

Call 866-387-4257 to schedule a demo today.

About IBM Watson Health

In April 2015, IBM launched IBM Watson Health and the Watson Health Cloud platform. The new unit will work with doctors, researchers and insurers to help them innovate by surfacing insights from the massive amount of personal health data being created and shared daily. The Watson Health Cloud can mask patient identities and allow for information to be shared and combined with a dynamic and constantly growing aggregated view of clinical, research and social health data.

For more information on IBM Watson Health, visit:

ibm.com/watsonhealth.

Footnotes

1 Sullivan, L. "The Current Status of Risk-Based Monitoring," Applied Clinical Trials, March 2015, <http://www.appliedclinicaltrials.com/current-status-risk-based-monitoring>

2 Tantsyura, V. et al. "Risk-Based Monitoring: A Closer Statistical Look at Source Document Verification, Queries, Study Size Effects, and Data Quality," DIA Journal: Therapeutic Innovation & Regulatory Science, November 2015, <http://dij.sagepub.com/content/49/6/903>

3 Motti, Eduardo F., M.D. "Today's Special in Clinical Trials: Risk-Based Monitoring. Have Investigators Been Served?", Pharmaceutical Outsourcing, March 26, 2015, <http://www.pharmoutsourcing.com/Featured-Articles/172811-Today-s-Special-in-Clinical-Trials-Risk-Based-Monitoring-Have-Investigators-Been-Served/>

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