QUINTILES®

Data-driven Trial Execution

Execute your risk-based monitoring trials *with confidence*

Improve your probability *of success*™

Optimize your clinical trial execution *with confidence*

Clinical development provides an invaluable service by developing new therapies. However, according to a 2016 study by the Tufts Center for the Study of Drug Development, it can take 10 years and $2.6B to develop these needed medicines with a significant portion attributed to trial operations.* Regulatory bodies have provided guidance on using risk-based monitoring to improve the operational efficiencies associated with clinical trial execution.

Transform your clinical development with the Quintiles approach to Risk-based Monitoring (RBM) – Data-driven Trial Execution.

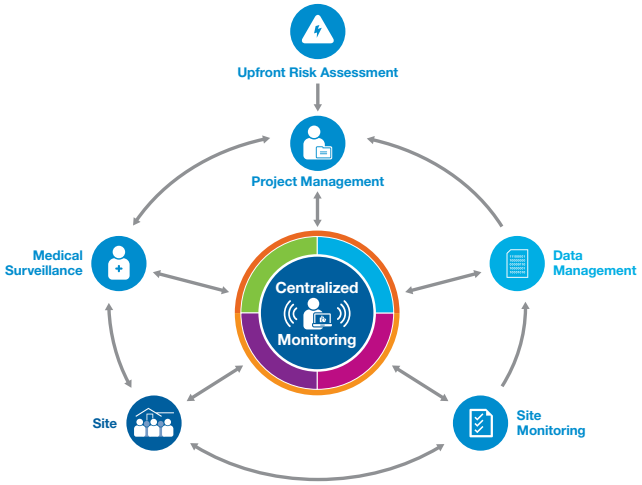
Technology advancements are delivering greater, and more timely, visibility into critical patient, site and study insights, enabling faster, more informed decisions throughout a study.

Now, with Quintiles' proven risk-based monitoring (RBM) approach, Data-driven Trial Execution, you can efficiently transform your clinical development efforts, using industry-leading analytics with enhanced data review processes, to optimize trial management and resource allocation.

Data-driven Trial Execution expands the RBM approach and is delivering improved data quality and faster query resolution time, with reductions in data entry and SDV backlog. Site management is reducing overdue action items at sites and the integration of holistic subject-level data review is reducing the amount of time higher-cost resources spend reviewing data for medically congruency.

Integrating people, process and technology

To help ensure the best outcomes of your clinical trials, Quintiles integrates the right expertise using the latest technology and proven processes.



Quintiles' RBM approach, Data-driven Trial Execution, is optimizing trial execution

A new approach for a new level of value

Improve quality	Uncover holistic insights with ongoing risk assessments and data surveillance
Enhance patient safety	Detect signals earlier and share data faster to get to analysis-ready data sooner
Increase site effectiveness	Leverage seamless technology to improve site communications and drive focus on patients
Drive efficiency	Centralize monitoring and operational support to standardize delivery and resolve queries faster
Reduce costs	Allocate resources effectively by focusing on high-risk areas with data analytics

*Innovation in the pharmaceutical industry: New estimates of R&D costs, DiMasi, Grabowski and Hansen, 2016

Execution with proven processes

- **Risk Assessment / Risk Management** – For your study, together we can quickly identify potential safety and quality issues from an operational and data perspective. To set the right risk management strategy, our therapeutically aligned teams of project managers, medics, biostatisticians and data managers perform an upfront assessment, informed by site feasibility and extensive industry data. We then monitor and evaluate the scientific and operational risk on an ongoing basis, using Key Risk Indicators (KRIs), data checks and advanced analytics.

  The output of the Risk Assessment process is to generate the Risk Assessment Mitigation Plan (RAMP), documenting how key risks will be mitigated through targeted monitoring of the critical variables and processes. It outlines the KRIs, triggers and analytics to drive the optimal level of remote, centralized and on-site monitoring for this particular study.

- **Project Management (PM)** – Your trial leverages highly trained Project Managers using proven technology to deliver high quality project outcomes. A Stage Gate approach uses best-in-class PM standards and tools to create a codified delivery approach.

- **Operational Excellence** – The integrated Global Delivery Network (GDN) project team uses Quintiles Infosario® technology platform to keep timelines, costs and outcomes on track across your global studies with comprehensive data-driven processes.

- **Study Start-up** – We minimize your trial start-up time by identifying the optimal Investigators through Quintiles' Site & Patient Network where we understand their therapeutic capabilities and access to even the most specific patient requirements. These insights enable us to provide up to 30% faster start-up timelines in certain therapeutic areas.

- **Centralized Monitoring** – Centralized Monitoring (CM) integrates core RBM processes with advanced analytics and KRI and trigger management to deliver holistic and timely insights at the patient, site, study and program levels, reviewed in near real-time to quickly identify potential issues, enabling faster resolution while providing full transparency to you and your study team.

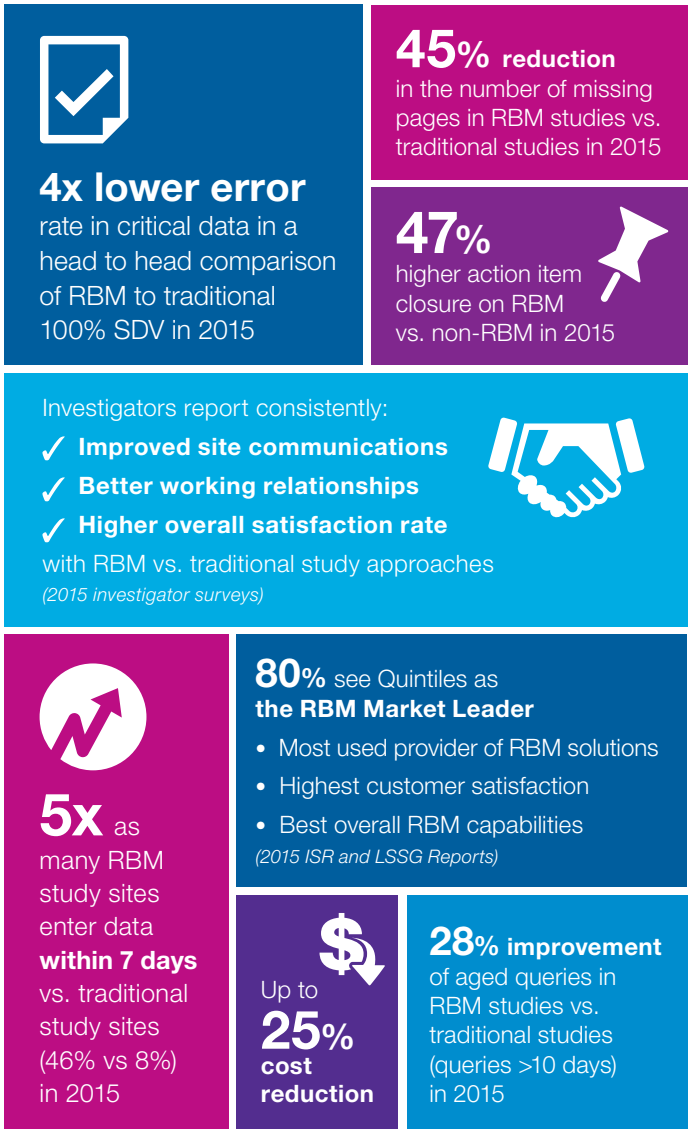
  – **Holistic medical data surveillance** – Predictive and Advanced Analytics drive site performance, patient safety and data quality while *proactively* resolving potential issues. We've optimized data management review processes using holistic patient, site and program data, *continuously reviewed by medically trained staff,* enhancing patient safety and data quality throughout your trial.

  – **Site monitoring & support** – Our Centralized Team assists Site Monitors (CRAs) with the review of monitoring triggers and in-house site management and supports CRAs with site visit preparation, allowing the CRAs to engage your sites on strategic areas such as patient recruitment or protocol adherence.

Drawing on our experience, regulatory guidance and TransCelerate methodologies, we'll work with you to develop a customized solution that upholds safety and quality while reducing source data verification (SDV) and the number of on-site visits, helping your studies to see decreased timelines and up to a 25% reduction in costs.

Delivering results through RBM

Our RBM studies are providing customers like you with extensive improvements in a multitude of key delivery areas. These improvements include:



Quintiles is the most used provider of RBM solutions. We deliver the highest level of customer satisfaction in the market.

Take the risk out of trial execution

As the RBM market leader, Quintiles has the experience to help accelerate your RBM implementation and transform your clinical development operations to realize the benefits as quickly as possible.

We have implemented RBM in more than 150 studies including more than 26,000 sites and over 260,000 patients. We have experience in multiple therapeutic areas, such as allergy/immunology, cardiovascular, central nervous system (CNS), infectious diseases, internal medicine, metabolism, oncology and rheumatology.

The Data Driven Difference®

How Quintiles Infosario® technology platform delivers deeper insight

According to the FDA, technology plays an important role in improving clinical trial oversight.

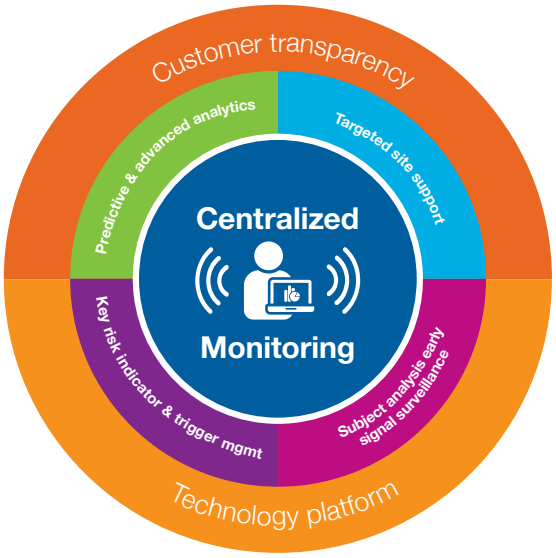
You gain greater insights and efficiencies for your studies from a comprehensive approach using innovative technology, our therapeutic expertise and enhanced processes to proactively manage your study to globally improve performance across every step of execution.

With our award-winning Infosario technology platform, you can:

- Enhance study and data quality through systematic, targeted cleaning and review
- Connect insights with holistic patient, site and study data through online dashboards
- Seamlessly integrate site, CTMS, EDC, labs, IVRS/IWRS and other data sources
- Resolve critical issues more proactively and efficiently with near real-time data insights
- Take timely, focused actions using comprehensive data visualizations of trends and signals

Accelerate your RBM development with Centralized Monitoring

Whether you are building your own RBM solution or need to enhance your Functional Service Provider (FSP) model with RBM, you can gain from our industry-leading RBM approach with a highly adaptive standalone Centralized Monitoring capability, which integrates our operational expertise, data integration, technology, predictive and advanced analytics, and site and patient management to speed your time in realizing the benefits of RBM for your trials.



Predictive & advanced analytics – Statistically driven insights for site and study/project management to proactively identify risks and prevent issues

KRI & trigger management – Identify and manage KRIs to reduce risk throughout the study

Targeted site support – Improved site level data flow and visit preparation for increased study compliance

Subject-level data review/early signal surveillance – Holistic subject review improves patient safety by seeing issues earlier, ensuring medical congruency

Contact us today to learn how Quintiles' proven approach to risk-based monitoring can provide the insight and value you need.

Contact us

U.S. Toll free: +1 866 267 4479
U.S. Direct: +1 973 850 7571
Europe and other areas: +44 203 564 4649
Asia Pacific: +65 6602 1245
Website: www.quintiles.com/rbm
Email: clinical@quintiles.com

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