

A Better Approach to Risk-based Monitoring

Execute confidently with Quintiles

The situation: Need to transform clinical development



10 years and \$2.6B
to develop a new drug*

*Source: Tufts Center for the Study of Drug Development



100% SDV not optimal for the majority of trials



Siloed data not ideal to minimize risk or maximize value


The challenges in clinical development:

 <p>Study protocol complexity</p>	 <p>Finding right sites & patients</p>	 <p>Budget constraints</p>
 <p>Speed to market</p>	 <p>Change management</p>	 <p>Data integration complexity</p>

The need: Process data more efficiently to reduce risk, improve quality and patient safety

The solution: Quintiles' approach to risk-based monitoring, Data-driven Trial Execution

Reducing risk and cost	Improving data quality	Enhancing patient safety
<ul style="list-style-type: none"> • Upfront and ongoing risk assessment • Adaptive Centralized Monitoring model • Increased study quality and management • Faster, more informed decisions • Reduced on-site visits • Optimized resource allocation • Predictive analytics identify potential risks 	<ul style="list-style-type: none"> • Advanced analytics drive timely actions • Real-time data entry and site communication lowers error rate, reduces aged queries and missing pages • Medically trained staff protect study integrity • Fully integrated data surveillance via Quintiles Infosario® Technology portal 	<ul style="list-style-type: none"> • Predictive/advanced analytics identify/resolve issues – at site and patient level • Timely site communication and compliance • Places focus on sites, data, patients, events where needed most • Medically trained staff review near real-time data to identify patient trends and ensure medical congruency



The value promise: Execute your RBM trials with confidence by partnering with the RBM market leader to optimize your clinical trial


The difference:

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Experience
More RBM studies underway delivering improved data quality, efficiency and enhanced patient safety
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Usage
The RBM market leader as most used RBM provider vs. competitors*
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Satisfaction
Delivering the highest level of RBM trial satisfaction in the market, according to clinical decisions makers
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Speed
4x as many RBM sites enter data within 7 days vs. traditional sites
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Efficiency
4x lower error rate in critical data using RBM vs. traditional SDV
- 

Therapeutic expertise
14 Therapeutic Centers of Excellence

*Source: November 2015 ISR Risk-based Monitoring report



>26,000
sites

>150
studies



>260,000
patients