

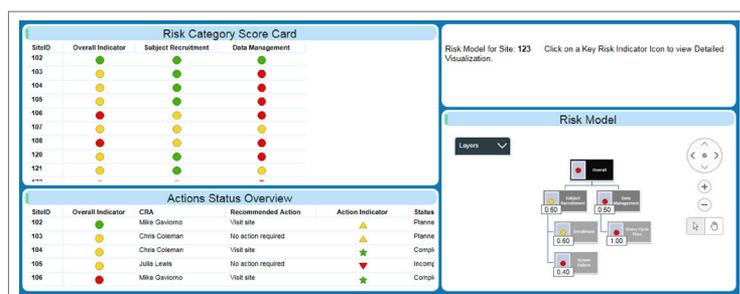


The new ICH E6(R2): Guideline for Good Clinical Practice from the Food and Drug Administration, European Medicines Agency and Pharmaceuticals and Medical Devices Agency are now supportive of risk-based monitoring as a method to optimize clinical trial operations and improve the overall drug development model.

PERKINELMER SOLUTIONS FOR RISK-BASED MONITORING

Automation and Time Savings

PerkinElmer offers an innovative approach for risk-based monitoring that leads to a reduction in the number of physical clinical site inspections while preserving clinical trial data quality and ensuring patient safety. With PerkinElmer's solution for risk-based monitoring, the effort spent on complete source-data verification can be significantly reduced. The resulting savings (in both time and costs) allows for better data analysis and better protection of subjects without multiplying costs. Clinical operations become more adaptive by aligning appropriate monitoring plans based on risk scores versus traditional calendar metrics. Onsite or remote monitoring (via lab portals, eDiaries, EDC, etc.) and centralized statistical monitoring for data surveillance can be determined to be most efficient. Statistical monitoring can be used to trigger CRA investigation and action planning. This data-driven monitoring approach provides risk assessments that identify and evaluate key risk indicators such as high query counts, screen failures, early withdrawals, and high site-time-to-data-entry. These findings can be shared and collaborated upon with site monitors irrespective of their location.



Complete overview of the risk model and action status, with visibility into specific risk triggers for each site.

AT A GLANCE

Leveraging common clinical data sources, advanced statistical methodologies, the TransCelerate framework and cutting-edge visualizations, PerkinElmer's solution for risk-based monitoring shifts clinical monitoring from frequency-based to proactive, comprehensive risk driven monitoring.

BENEFITS

Fastest to Actionable Insight

Increase agility by providing clinical development users throughout the organization with unmatched speed and flexibility to anticipate, answer, and act on answers to risk monitoring questions.

Visibility into the Unknown

Uncover trends and patterns that represent risk or opportunity through intuitive visualizations, analytic dashboards, and applications. Connect to clinical data sources and include disparate clinical, operational and safety data in your risk monitoring program.

Self-Service Discovery

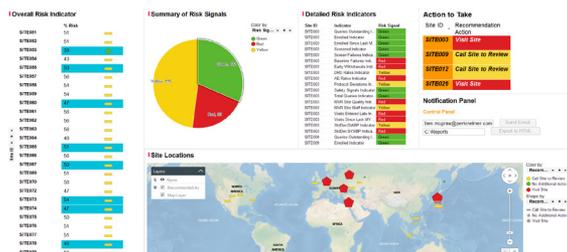
Use self-service discovery to drastically reduce reliance on IT and eliminate delay related to data preparation, report building, and spread-sheet version control.

Universal Adaptability

Empower the broadest spectrum of clinical development users across the widest range of analytic use-cases and processes. Whether you need clinical operations dashboards delivered on a tablet, exploratory applications on the desktop, or interactions with a predictive application running in a web browser, PerkinElmer delivers.

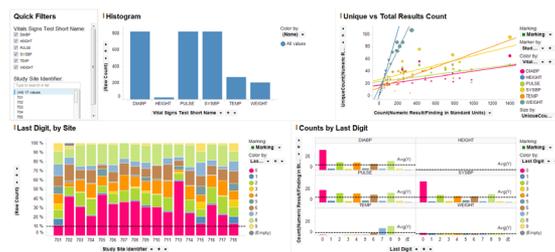
ATTRIBUTES AND CAPABILITIES

Recommend Actions



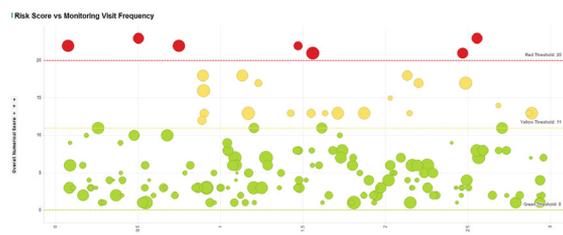
Risk scores can be fed into a monitoring plan tailored to address important and likely risks identified during risk assessment. The plan also includes the ability to recommend actions based on business rules.

Adjust and Re-Calculate



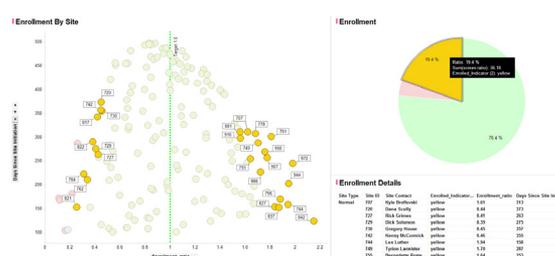
The number of visits since the last monitoring visit threshold can easily be adjusted, and recommended actions can be automatically re-calculated based on results.

Visualize Overall Risk



Monitoring visit frequency can be compared to risk scores. The comparison can be viewed in the context of the severity of risk, number of subjects randomized, and the number of monitoring visits per month.

Hide the Complexity



Program managers, country managers, study managers, and CRAs can leverage easy to understand visualizations to incorporate risk-based monitoring practices without getting bogged down in data aggregation and statistical modeling.

“PerkinElmer is way ahead of other vendors offering RBM solutions. We are extremely happy with the work that your team is doing on our RBM project.”
Top 5 Pharmaceutical Company

To learn more about our solutions for clinical development, please visit www.perkinelmer.com/ClinicalInformatics

It is the responsibility of the end user to install and validate PerkinElmer solutions within the end users quality systems in accordance with their policies and standard operating procedures.

PerkinElmer, Inc.
 940 Winter Street
 Waltham, MA 02451 USA
 P: (800) 762-4000 or
 (+1) 203-925-4602
www.perkinelmer.com



For a complete listing of our global offices, visit www.perkinelmer.com/ContactUs

Copyright ©2015, PerkinElmer, Inc. All rights reserved. PerkinElmer® is a registered trademark of PerkinElmer, Inc. All other trademarks are the property of their respective owners.