

# Next Generation Al-driven Risk-Based Quality Management (RBQM) Solution:

Elevate Your Clinical Trial Management

In today's complex and fast-paced clinical trial landscape, ensuring the highest quality standards is essential. EDETEK is combining its deep domain expertise with advanced technologies such as AI/ML, advanced analytics, and integrated data pipeline to launch a next generation RQBM solution. This RBQM solution offers a comprehensive, real-time approach to managing trial quality and monitoring risks, from data integration to issue resolution. With advanced analytics and seamless integration with EDETEK's innovative technology, you can trust our CONFORM<sup>TM</sup> platform to deliver superior trial oversight.

### **Key Features**



## 360 Real-Time Data Integration

Experience seamless, real-time integration of clinical, operational, and safety data from multiple sources. Our RBQM solution consolidates data into a single, actionable view, ensuring that all stakeholders have access to up-to-date insights.



## Data Standardization

We ensure your data is harmonized and standardized, allowing for consistent analysis and reporting across all study sites. This ensures the integrity of your data and allows for streamlined decision–making.



# Comprehensive Monitoring

Monitor your trials with a combination of traditional and risk-based approaches, allowing for both routine and targeted assessments. Our solution supports both supervised and unsupervised monitoring, giving you flexibility in how you track and manage trial performance.



#### Risk-Based Monitoring (RBM)

Prioritize your monitoring efforts where it matters most. Focus on high-risk areas and critical data points to optimize resources and ensure the highest quality standards throughout your clinical trial.



## Data Visualization & Dashboards

Access patient profiles, study dashboards, and advanced data visualization tools that provide you with clear insights into trial progress. Easily monitor KPIs, track deviations, and make informed decisions quickly.



#### Safety and Efficacy Monitoring

Our platform integrates safety and efficacy monitoring to ensure patient safety and regulatory compliance. Track adverse events, monitor safety signals, and ensure the efficacy of your trial interventions, all within a single system.





## Issue Tracking & Resolution

Track, prioritize, and resolve issues with built-in issue management tools. Our solution provides a transparent audit trail for issue resolution, ensuring accountability and reducing risks of non-compliance.



## Supervised/Unsupervised Monitoring

Harness the power of advanced analytics with both supervised and unsupervised monitoring methods. Automatically detect patterns, outliers, and trends in your data to proactively manage risk and improve trial efficiency.



## Seamless EDETEK Integration

Our RBQM platform integrates seamlessly with EDETEK's innovative clinical trial solutions, providing you with enhanced capabilities in data management, regulatory submissions, and trial optimization. With EDETEK's solutions, you can automate workflows and achieve greater control over the entire trial lifecycle.



## Therapeutic/Disease-Area Accelerators

Our RQBM solution has prebuilt accelerators that can cut lead time to launch the solution for specific TA/disease areas (oncology, immunology, etc.) and increase adoption of industry best leading practices.

## Why Choose Our RBQM Solution?



#### AI/ML-Powered Insights

leveraging the latest advancements in AI and ML to provide unparalleled insights into your clinical trials. By employing both supervised and unsupervised monitoring techniques, we ensure that no critical data point goes unnoticed.



#### Intuitive Data Visualization

The intuitive data visualization tools allow you to spot trends, identify outliers, and make informed decisions quickly. With our patient profiles and study dashboards, you'll have a 360-degree view of your trial's progress at your fingertips.



# Comprehensive Safety and Efficacy Monitoring

Safety and efficacy monitoring are at the heart of our system, ensuring that patient's well-being is never compromised. Our robust issue tracking and resolution features make it easy to address concerns promptly and maintain a clear audit trail for regulatory compliance.



#### Seamless Integration

By integrating information from EDETEK, we provide a comprehensive solution that covers all aspects of clinical trial management, from data collection to analysis and reporting.

#### **Ready to Transform Your Clinical Trials?**

Contact us today for a personalized demo and discover how our RBQM platform can revolutionize your approach to clinical research. Together, we can accelerate the development of life-changing therapies while maintaining the highest standards of quality and patient safety.