premier research
Built for Biotech™

Premier One Ecosystem

Delivering clarity amid the complexity

NEXT

Fully Integrated Ecosystem Fuels Biotech Innovation

The Premier One Ecosystem aggregates all the data captured within our ePremier environment. The ecosystem also represents Premier Research's processes for data analysis related to administrative and financial data, study management data, and patient data. Among systems contributing to the ecosystem are risk monitoring, clinical trial management, electronic data capture, and time and expense data.

- **Data aggregation:** The ecosystem aggregates all study-related data in one centralized system for rapid, informed insights
- **Real-time analytics:** Highly trained staff conduct near-real-time analysis, considering data from the perspectives of risk, efficacy, and process improvement
- **Centralized collaboration:** Coordinated teams for centralized and on-site monitoring optimize data quality and better manage compliance risk

In short, we engage, lead and provide end-to-end visibility to enhance study-wide communication, speed enrollment, improve safety, and reduce risk.

The Premier One Ecosystem integrates disparate data, improves processes and supports the careful management of all study data.

85% of Clinical Trials Have Delays; 95% of Those Are >1 Month

The Issue	ePremier Solution
> 50% use spreadsheets to manage data	Electronic data tracking and monitoring for greater study insight and reduced error risk
Data resides in disparate places	Data standardizations and the ability to integrate
Failure to predict and address risk	Risk-based quality management tailored to study protocols and endpoints

Integrated to Deliver Real Value

Our Built for Biotech operational model focuses on continued process optimization, transparent data flow, and expertise in adaptable trial execution. When study data flows into our ecosystem, our optimized process makes data capture logical, obvious, and easy.

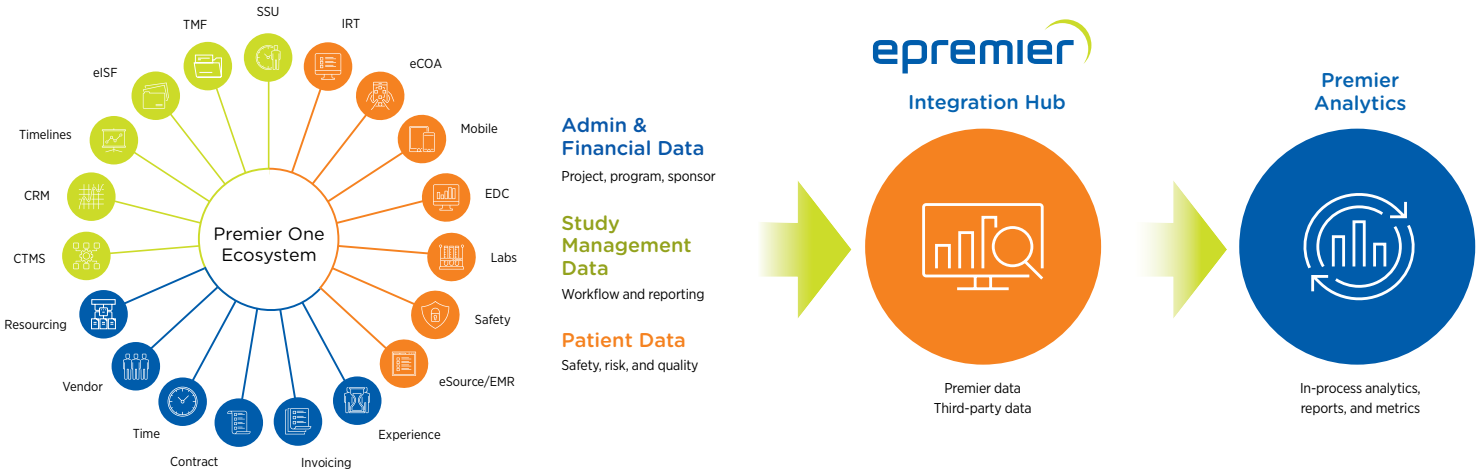
For instance, remote monitoring access enables us to easily and regularly view data anomalies across sites and patients, addressing potential risks before they become issues. That, in turn, results in greater efficiencies, reduces rework costs, and increases your study's effectiveness. This integration is the heart of the Premier One Ecosystem.

A customized workspace provides one central place to track activities, expanding visibility and driving the highest quality management.

Universal Technology Platform Delivers Critical Insights

Flexible and precise, the Premier One Ecosystem enables processes, applies rigorous standards, and supports the careful management of all study data to minimize risk and meet regulatory requirements. We begin by fully integrating all the data across the study, from contracts and vendors to timelines and reports to every aspect of patient data. The result: clear, centralized communication, cross-functional data analysis, and greater transparency.

Technology-Enabled Processes



We're built for biotech, and we have one goal: to help our customers transform life-changing ideas into reality.

We're clinical development experts focused on helping today's most innovative biotech and specialty pharma companies take their best ideas from benchtop to bedside.

ePremier Makes Patient Data Capture Logical, Obvious, and Easy

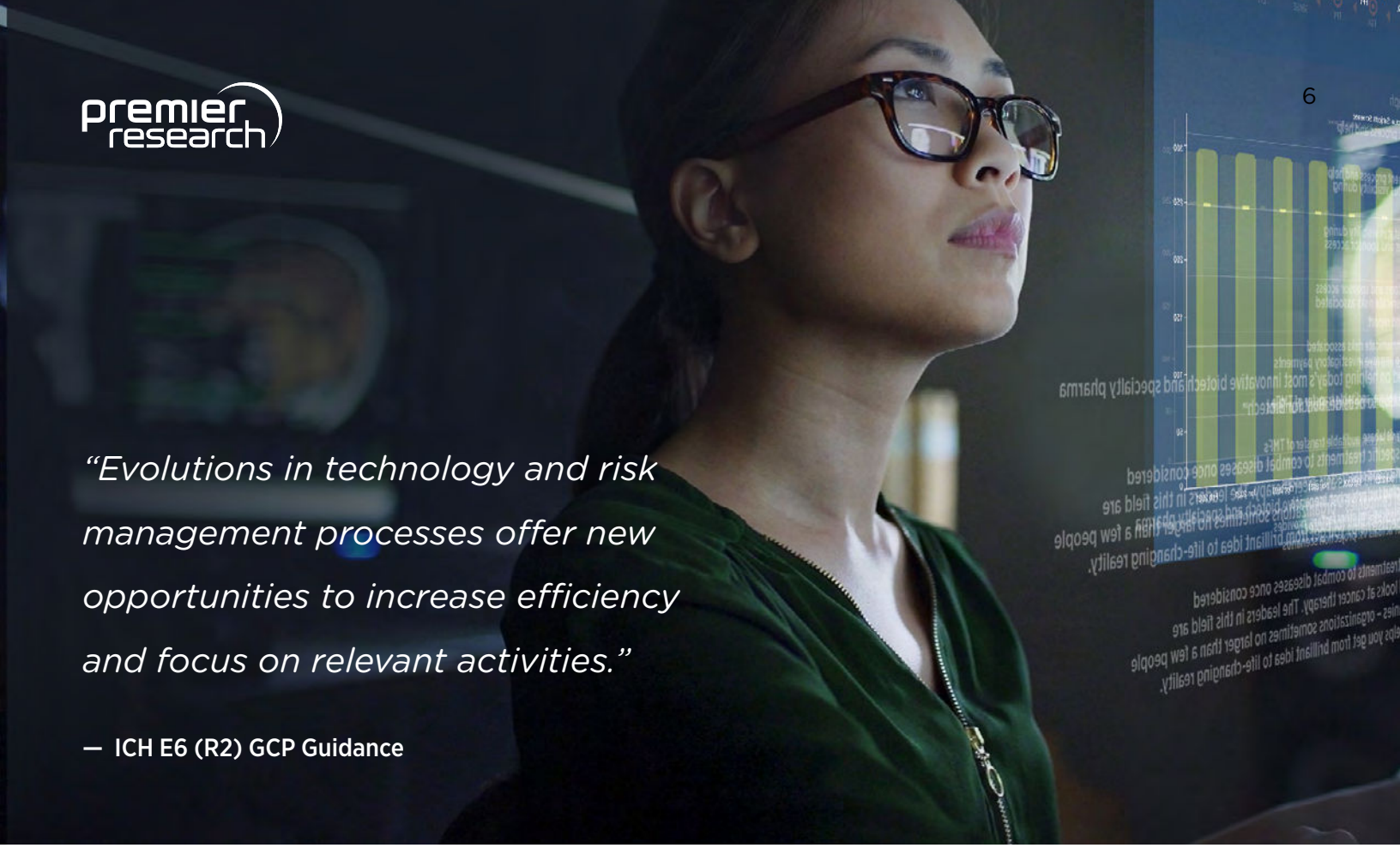
A study-wide integration hub, ePremier automatically captures critical patient data from all sources: EDC, electronic patient-reported outcomes (ePRO), laboratory, interactive voice and web response systems (IVRS/IWRS), electronic clinical outcome assessment (eCOA), and mobile health (mHealth) devices. Centralizing this data simplifies analysis, supporting timely risk mitigation.

ePremier:

- **Captures the right data** from the specified system at the right time
- **Aggregates data across all sites** to provide simultaneous access across study teams
- **Verifies the data** as complete, accurate, and specific to our needs
- **Supports critical thinking** with study-, country-, and site-specific data flows
- **Enables consistent, centralized routine assessment** of scientific and procedural parameters
- **Improves overall data quality** by identifying outliers and trends in near real time

CTMS+ Supports Risk-Based Quality Management

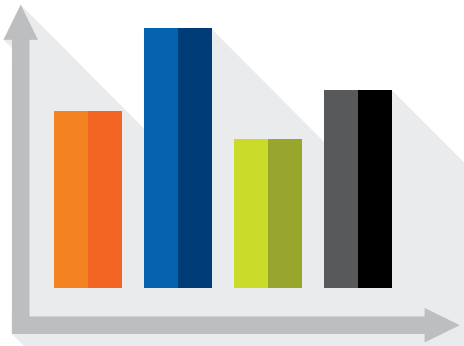
Our unique, system-agnostic Clinical Trial Management System Plus (CTMS+) integrates all data related to study management — such as visit scheduling and reports — to help streamline workflows. Critically, it also supports risk-based quality management and central monitoring through flagged action items, protocol deviation tracking, and end-to-end study visibility.



"Evolutions in technology and risk management processes offer new opportunities to increase efficiency and focus on relevant activities."

— ICH E6 (R2) GCP Guidance

Integrated Analytics and Specialized Expertise Speed Critical Insights



Premier Analytics provides Premier study teams and sponsors access to a broad range of site and patient data — then applies statistical algorithms to support risk identification, quality management, and the regulatory requirements of ICH GCP E6 (R2).

- **Clinical Data Sciences department** consists of clinical research associates, clinical leads, data coordinators, and clinical data scientists who routinely review study data and monitor for risk
- **Ongoing in-process analytics, reports, and metrics** inform study decisions for sponsors and investigators
- **In-depth evaluation** of key risk indicators and other data disclose the root cause of issues
- **Clear communications** address systemic process issues and site behaviors

Hybrid Monitoring Reduces Risk and Improves Overall Data Quality

Our collaborative approach to monitoring combines highly trained clinical data scientists with on-site monitors, so the study team can better execute on regulatory requirements and data quality management.

Clinical Data Specialists remotely review study-wide data against prespecified study risks:

- Checking for outliers and trends on a consistent, ongoing basis
- Reviewing for missing or invalid data or unusual data patterns
- Assessing rates of data reporting, including adverse events
- Evaluating scientific and procedural trial parameters

Clinical Research Associates focus on study data while on site:

- Ensuring currency, accuracy, and quality of regulatory and other study documentation
- Tracking drug and/or device accountability
- Reviewing patient data for accuracy, quality, and consistency with the data points entered into the EDC system

As technology increasingly supports remote data capture through mHealth devices and direct capture of source data, we continue to evolve our processes to maximize study efficiencies and patient safety.

Customized Dashboards Visualize Insights

Data flows through the ePremier hub and displays on custom dashboards to spotlight analytics and enhance collaborative decision-making.

- Visualizations summarize data from multiple sources for transparency and ease
- Zoom and filter options enable detailed queries
- Reports support time, quality, and cost management

Risk Mitigation Is Integral to Every Step

Clinical trials face potentially study-ending risk daily: Enrollment is low or slow. Data is entered incorrectly. Endpoints aren't met. Worst, safety issues that endanger patients are not caught promptly. Premier One Ecosystem is designed to mitigate these risks by flagging issues in real time and delivering crucial insights for timely decision-making.

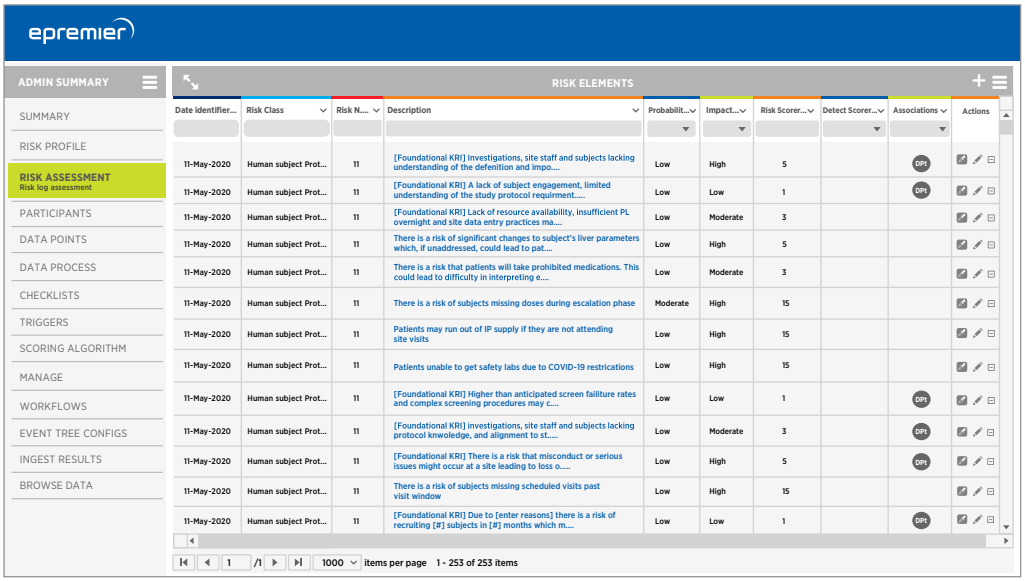
Our risk-based quality management application allows you to:

- Analyze data points, including those not captured but calculated
- Manage endpoint analysis and Data Safety and Monitoring Board (DSMB) meetings
- Create, manage, and resolve manual workflow items
- Dedicate interfaces that support patient and site review
- Create dashboards without needing a separate business intelligence tool
- Create checklists at the patient and site level that drive consistent data review and tracking across users
- Configure new alerts/triggers on any data point coming into the system
- Seamlessly integrate information covering all types of data, not limited to EDC, CTMS, and interactive response technology
- Manage multiple versions of the risk assessment
- Detect outlier data
- Predefine a site scoring model

We offer decades of experience in strategic development, global compliance, and therapeutics to ensure that your promising therapy isn't delayed by risk or limited resources.

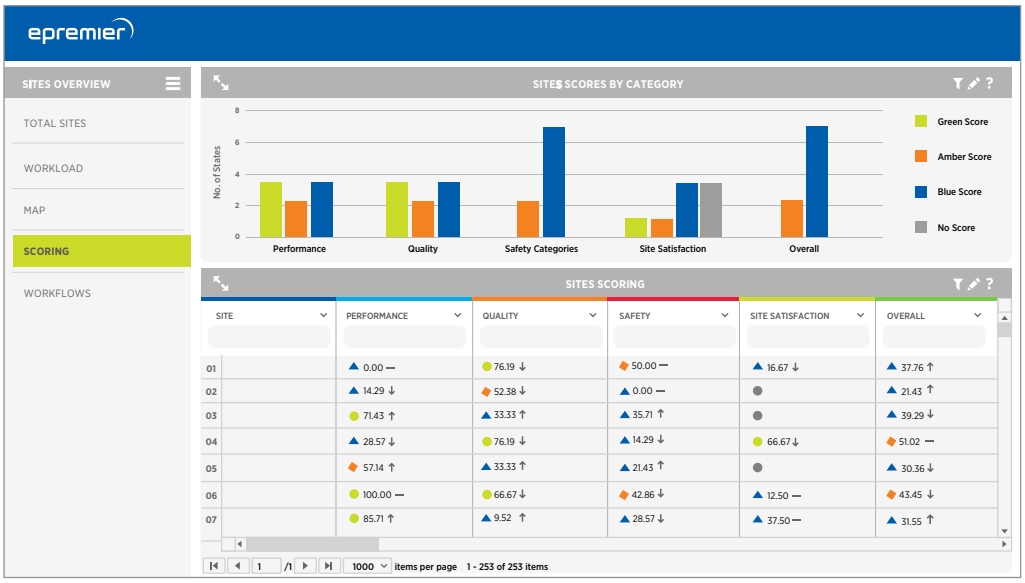
Built-in Risk Log

After aggregation and analysis, you can visualize site-wide data to clearly identify risk.

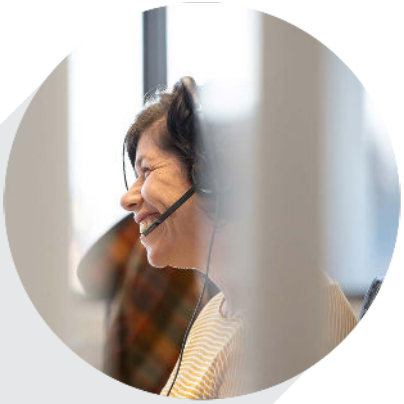


Monitoring Site Overview

Comprehensive site and patient scoring highlights unusual data patterns.



We're continually optimizing our processes to deliver the right mix of agility and knowledge to support our most innovative biotech and specialty pharma sponsors.



A Single Ecosystem Optimizes Trial Processes

While much is changing in the deployment of clinical trials, one thing is constant: the value of data. Beyond proving safety and efficacy, it provides valuable insights at every point of trial execution, from site selection to enrollment and from protocol development to execution. The Premier One Ecosystem adds highly trained specialists and carefully refined processes to our world-class technology, delivering a holistic structure to optimize your study.

We begin with direct data capture, saving time and improving quality, and then ensure that your data is monitored, reviewed, and analyzed to support timely action. The ecosystem:

- **Captures** quality data at the source, streamlining data collection
- **Removes** the potential for costly errors due to manual handling, manipulation, and translation into a system
- **Aggregates and visualizes** important data points managed through our data architecture
- **Ensures** ongoing, expert analysis to mitigate risk and maximize results
- **Supports** quality improvements through a carefully crafted monitoring process
- **Delivers** data transparency with sponsor access to dashboards and study insights

The result: Study data that is more complete, accurate, and available — and product development that is faster, safer, more efficient, and less costly — than ever before.

Three Keys to Improving Quality While Minimizing Risk

- **Securing the right data** from the specified system at the right time
- **Capturing the data necessary** to solve a problem, manage a challenge, or answer a question
- **Certifying and verifying the data** as complete, accurate, and specific to your project's needs

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