SOLUTION BROCHURE

Clinical Analytics Solutions

Real-Time Data Access Drives Analytic Efficiencies to Bring New Drugs to Market Faster

revvity signals

Increasingly complex clinical trials require a fast, flexible data and analytics platform

Biopharmaceutical companies are broadening their pipelines at an increasing pace and, while managing the data of a single clinical trial has always been a challenge, the pressures to deliver multiple studies on time and on budget have only increased. A central challenge for trial managers is to unify multiple disparate data sources, retain data quality, and then analyze these data to ensure the study remains on track. To ensure subject safety and understand drug efficacy, pharmaceutical and biotech companies must be able to access high-quality trial data in real-time, foster collaboration across the development team, and leverage analytics to provide meaningful clinical and operational insights.

Real-time data fosters efficiency

Data is the bedrock of any successful clinical trial. But key to improving the velocity of trials is real-time access to clinical trial data and the ability to apply advanced analytics to get a complete picture of patient safety, treatment efficacy and trial progress.

Pipeline growth and, ultimately, drug approvals are the lifeblood of pharmaceutical and biotech companies, but challenges abound including:

- Length and cost of clinical trials
- Increased complexity of trials
- Real-time data access and sharing of data between sponsors and CROs
- Regulatory changes including new trial designs
- Methods to unify data across the trial to break down data silos

Drug developers can effectively tackle these challenges using a fast and flexible data and analytics platform to empower data-driven decision-making. A centralized analytics platform built to support today's clinical study requirements will increase trial efficiency, provide actionable analytic insights, automate data collection and harmonization leading to better collaboration, support safety and efficacy decision-making, and enable a singular view across a company's entire candidate portfolio. To accomplish this, trial managers require:

- Time-relevant views of patient data and clinical trial progress
- Fast, visual detection of safety signals to drive better trial outcomes
- Cross-functional mechanisms to evaluate safety data and make rapid study decisions
- Rapid, agile deployment and user adoption; reduced IT reliance

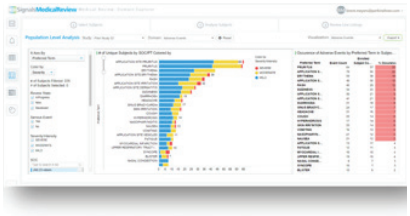
Analytics Modules

Clinical trials can generate vast amounts of critical data, but gleaning insights from these data is challenging for many organizations. In designing a collection of analytics modules to support clinical development, Revvity Signals built a flexible platform to deliver clinical trial data insights in real-time.

CLINICAL DATA REVIEW. A robust analytics tool that provides clear visualizations to enhance the monitoring of safety, efficacy, and data quality. Clinical data review facilitates fast and accurate data discovery. Detecting safety signals faster using innovative advanced analytics can accelerate decisions and reduce overall risks.

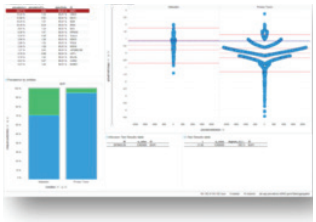
Clinical Data Review

MEDICAL REVIEW. Increase the efficiency of medical data review with visual analytics and workflows. Medical monitors can browse, search, and analyze trial data visually, track their progress, and share their results. Insights derived from medical data are streamlined, providing both population data and visualizations and line listing review for quick drill down to the individual patient level, which can detect early safety signals or study bias.



Medical Review

LINE LISTING REVIEW. Allows study personnel to review, query and track line listing data and collaborate cross-functionally during their review. By providing line listing review status and an audit trial of activity, it enhances regulatory compliance while saving hours of time for safety review and data management teams.



Efficacy Analyses

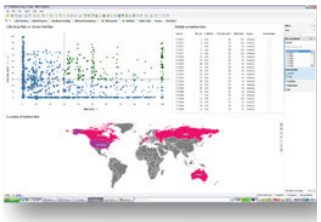
PHARMACOVIGILANCE AND SAFETY. Visual representations allow for easier and faster identification of issues related to patient safety, case processing and reporting compliance. This accelerates response times to any safety issues that arise while also supporting regulatory compliance. Analytics capabilities include safety case analysis and safety signal detection.

Pharmacovigilance

RISK-BASED MONITORING. RBM dashboards empower a risk-based approach to site monitoring through key risk indicators or centralized statistical models. These data-driven insights can help clinical trial managers more effectively deploy monitoring resources to optimize performance of trial sites while lowering costs and improving data quality and patient safety.

Risk-Based Monitoring

CLINICAL OPERATIONS. Enhance operational effectiveness with timely visual insights into study start-up, recruitment, site performance, budget, milestone tracking and more. Identify and communicate study status and potential challenges to the entire team. View operational insights at the portfolio, country, and study level.



Operations

Access and visualize trial data

Revvity Signals provides the fast, and flexible analysis tools clinical trial managers need to support pipeline growth and speed promising treatments to market. This includes integrated functionality for Clinical Data Review, workflow-based Medical Review, Line Listing Review, Risk-based Monitoring, Pharmacovigilance, Clinical Operations, Efficacy Analysis, and more. This functionality can be easily modified to support therapeutic area or specific trial design requirements.

The engine behind the Clinical Analytics Solutions is TIBCO® Spotfire®, an enterprise-class platform for building and deploying interactive dashboards, visualizations, and predictive and event-driven analytics. Spotfire is used to quickly uncover insights from clinical trial data at biopharmaceutical companies of all sizes. Users create data visualizations via Spotfire's easy-to-build and easy-to-use dashboards, empowering clinical teams to uncover novel, actionable data insights. Spotfire's unified visual analysis and preparation interface allows clinical study teams to quickly clean and enrich data while performing data analysis, and its integrated predictive analytics capabilities allow trial personnel to stay ahead of the data to proactively manage clinical trials.

Built specifically to facilitate clinical trial data insights, the Clinical Analytics Solutions provide:

Data source flexibility. The platform has the ability to read multiple data sources including electronic data capture (EDC), electronic medical records (EMRs), electronic health records (EHRs), claims, lab reports, pathology, imaging, operational trial data, and ontologies.

Technologies connecting clinical templates and TIBCO® Spotfire® to relational databases, EDC systems, document stores, NoSQL, file shares, and even social media platforms. The platform facilitates data source connectivity and automated refreshes to provide timely access to trial data. Access data in virtually any EDC system or use specific connectors to leading EDC solutions.

Data enhancement. Aggregate data from multiple, disparate data sets and organize and standardize the data as needed to support analysis and collaboration.

Rapid insights. Deliver critical insights quickly using Spotfire's advanced analytics and visualization to uncover and address safety, efficacy, data quality, operational, or other critical issues in a timely manner.

Industry-ready solutions. Task-specific templates, from clinical data review to drug safety, are designed specifically to meet the requirements of clinical researchers to make data-driven decisions using rapid data insights.

Key capabilities to ensure trial objectives are achieved

Clinical trial sponsors rely on quality clinical data in their drive to protect patient safety and measure treatment efficacy. Revvity Signals delivers a single platform to manage the distributed, disparate clinical data sets and provide real-time insights across a single trial or the enterprise. The flexible set of tools, combined with Spotfire's data analytics and visualizations and Revvity Signals' domain expertise, provide:

1. ***Speed, Scalability, and Flexibility***
   Real-time data visualizations for fast and efficient analysis
   Access to distributed data across multiple data sources

Speed, Scalability, and Flexibility for fast and efficient analysis

Your clinical trial no longer needs to wait for relevant data from disparate trial sites to be gathered prior to analysis. As a comprehensive clinical data platform, the Clinical Analytics Solutions facilitate analysis of trial safety, efficacy, and data quality in real-time. Clinicians and Study Managers can more easily spot important findings as the trial progresses and can collaborate around shared data with other professionals, leading to more vital insights and accelerated decision-making. Purpose-built clinical analytics integrated with Spotfire deliver robust analytical capabilities that allow drug sponsors to add capabilities most needed for the success of their trial. Multiplied across an entire portfolio, you gain a truly holistic view of all your trials.

2. ***Analytics and visualizations***
   Decision support for speeding efficacious drugs to market
   Tools to reduce study complexity
   Unlock study insights

Study complexity, data volume, and data latency can lead to bottlenecks in the efficient management of clinical studies. The Clinical Analytics Solutions unify disparate data sets with modular, adaptive analytics designed specifically for clinical trials, to present complex data visually instead of buried in spreadsheets. This unlocks insights vital to proper evaluation of clinical studies. These solutions help to analyze and visualize:

- Clinical data review with KPI analysis and early site identification for adverse events
- Pharmacovigilance and safety data
- Risk-based monitoring, including for risk indicators and site management
- Medical review, including Line Listing Review, to drill down from population to single-patient data, and early identification of study bias.

3. ***Integrated tools to communicate workflows***
   Holistic view of all trial data
   Data-sharing between sponsor and CROs
   Greater collaboration

Integrated tools to communicate workflows and improve collaboration

Inflexible, siloed tools prevent a holistic view of the clinical trial and hinder cross-functional collaboration for trial personnel. For study teams, sponsors, and CROs to effectively share high-quality data, they need a seamless workflow in a single environment. Without the need for data to “leap” across data silos, Revvity Signals delivers a centralized environment that combines real-time data access with integrated analytics and workflows to support proactive management and decision-making in clinical trials.

One Team One Goal – Fast, Flexible Services for Clinical Analytics

Services provided by domain experts in both clinical trials and analytics

Revvity Signals understands that not all clinical trial sponsors are alike. While the Clinical Analytics Solutions, including TIBCO® Spotfire® and clinical-specific templates, can be employed as a self-service offering, many sponsors benefit from the clinical development and analytics expertise of Revvity Signals' Clinical Analytics Practice. Our practice provides significant value to organizations lacking sufficient IT or analytic resources as well as organizations that want to use internal resources more efficiently.

With our team of application experts, Revvity Signals will partner with your team to:

- Deliver clinically relevant visualizations typically within six weeks of project kick-off;
- Help your organization quickly adapt to the shifting needs of your trial;
- Empower your staff to be self-sufficient with the Clinical Analytics Solutions

The Clinical Analytics Practice delivers a wide range of services for designing, deploying, and managing solutions that align with your organization's clinical analytics needs. Service offerings include:

- Implementation Services for Spotfire and Rave Connector
- Services to Support your Software Validation
- Clinical Module Delivery and Customization
- Configuration & Integration Services
- Knowledge Transfer & Education Services

Revvity Signals experts understand technology and the science of our customers. We apply that expertise to deliver solutions that meet and exceed customer expectations.

200

Professional Services Staff Globally

75%

Advanced Scientific or Technology Degrees

350

Projects Completed per Year

Transform Clinical Development with Rapid Insights

Clinical research has entered a new era, one that requires real-time analytics and visualization to allow trial leaders to work collaboratively and to develop, at the click of a mouse, deep insights that enable proactive study management. Clinical analytics facilitate improved efficiency, along with faster and better-informed go/no go decisions for drug candidates. By combining TIBCO® Spotfire® with a flexible set of clinical trial analytic modules and our deep clinical trial and analytics expertise, Revvity Signals provides a comprehensive technology and services offering focused on evaluating data quality, patient safety, and treatment efficacy. And most importantly, the data-driven decisions informed by these insights can help improve the lives of patients by speeding the most promising medicines to market.

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To learn more about the Revvity Signals Clinical Analytics Solutions and how fast, and flexible analysis and visualization can support pipeline growth and speed promising treatments to market, visit:revvitysignals.com/solutions/clinical-translational

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