WHITE PAPER

Empowering Clinical Trial Sponsors with Analytics

revvity signals

Making quick and accurate decisions during a clinical trial is critical for keeping patients safe and studies on track. However, increasing trial complexity, new data types, and a growing reliance on contract research organizations (CROs) can make it difficult for sponsors to access and analyze the data they need, when they need it.

This article examines data challenges faced by sponsors and the underlying problems driving those challenges. It also details fast and flexible new processes and solutions designed to help overcome these challenges by serving sponsors' ever-increasing need to analyze complex data. These solutions provide actionable insights that make safety signals easy to detect and investigate while easing the burden of meeting regulatory requirements.

TOP DATA CHALLENGES FACED BY SPONSORS

Getting the Right Data at the Right Time

One of sponsors' top challenges today is a lack of real-time access to the clinical trial data they need to make swift, well-informed decisions. In addition to ensuring patient safety, this data helps sponsors avoid protocol problems, enrollment issues, skewed trial results, and paying for patients who do not meet criteria. According to a Pharma Intelligence / Oracle research report, more than 60% of surveyed professionals involved in clinical data management identified accessing clinical trial data as a top challenge.[1]

Sponsors encounter difficulty accessing trial data because it is often controlled by CROs, as well as other outside groups and vendors. This reliance on third parties prevents responsiveness and agility, meaning sponsors often wait days or weeks to receive requested data. Even when the data does arrive, it is not always in a useful format that clinical teams can quickly act upon.

Data is Distributed Across Multiple Systems

As the types, volume, and sources of data collected during trials grow, so do the number of systems used to collect and store this data, making it difficult to assemble all necessary data to perform analytics.

The trend toward decentralized trial strategies has escalated the use of new technologies, such as wearable devices, that collect huge volumes of continuous data in novel formats. Biomarkers, increasingly used to select patients for inclusion in a trial, represent another new data format. Biomarker data use in a trial requires not only collecting the information necessary to select participants, but also substantiating how biomarkers impact the success or failure of the trial as it progresses.

Further, these new data formats often originate from multiple sources, including various labs or CROs. A recent report from Tufts University found the average number of investigative sites conducting Phase II and Phase III trials increased 33% from 2009-12 to 2017-20.[1] Multiple data sources and formats not only complicate sponsor oversight of data collection and analysis, they also can lead to issues with data completeness, data quality, and data cleaning.

Inflexible or Irrelevant Analytical Tools and Processes

Although clinical trials have changed a great deal, sponsors' methods for reviewing and analyzing data have not kept up with the changes. Many of the analytical tools used today do not work across multiple use cases and cannot be easily adapted to meet new needs as they arise.

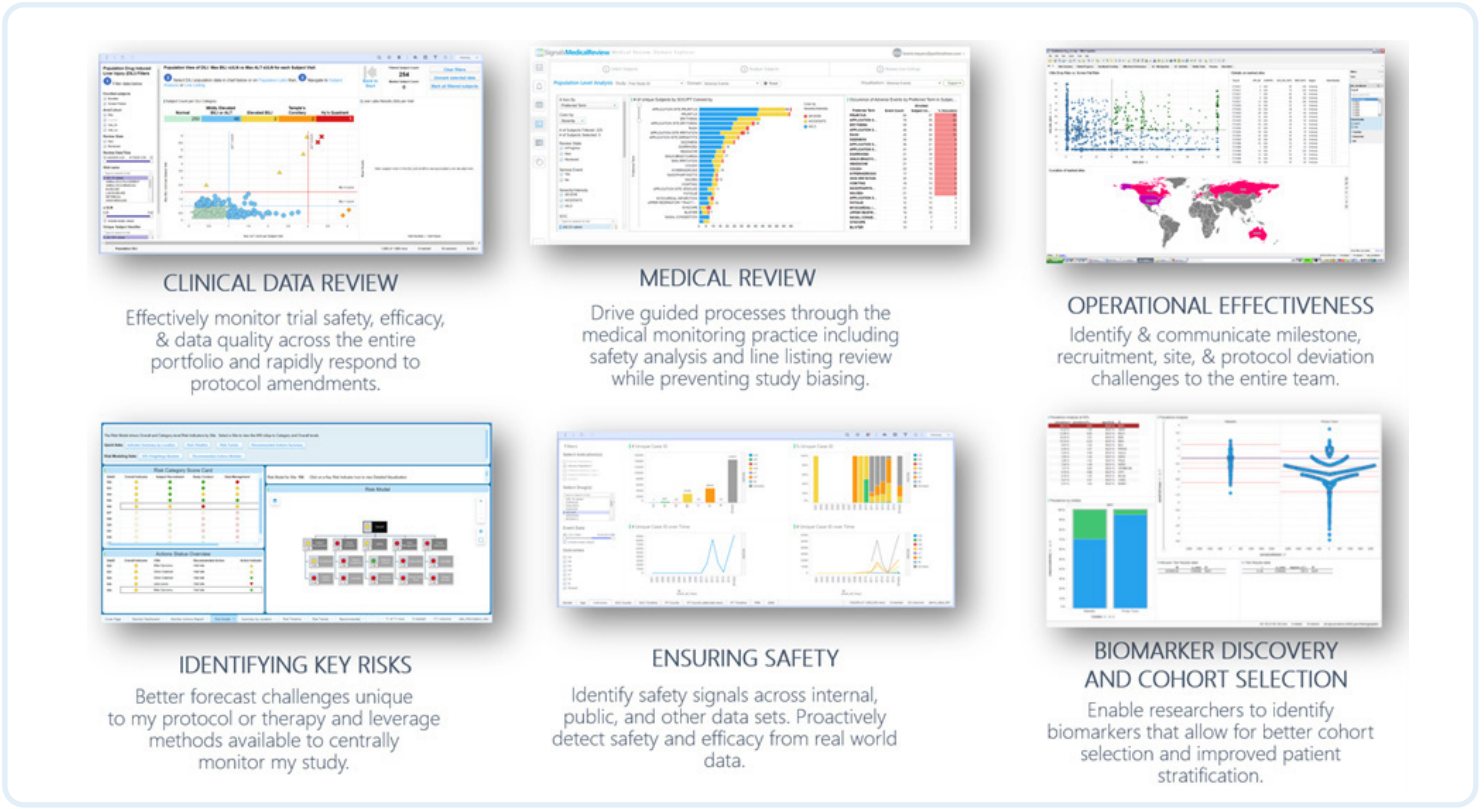
Clinical study teams often carry out review processes using Excel, paper printouts, or PDFs. These strategies make it difficult for various teams involved in the clinical trial to collaborate because they must e-mail data back and forth. Scrutinizing data row by row does not reveal relationships across data domains and inhibits reviewers' ability to track progress. In addition, many existing or competitive analytic tools cannot answer study-specific questions, enable timely decision-making, or provide access to data as they are entered into source systems.

Data analysis can be further complicated by new trial designs, protocol amendments, and the growing number of endpoints used in trials. Phase II and III protocols typically involve more than 260 procedures per patient (a number that continues to grow) and include approximately 20 endpoints.[1] Sponsors need analytics tools flexible enough to adapt to mid-study protocol amendments — which are quite common, especially during Phase III trials — and allow data from one trial to be reused for multiple indications.

Flexible analytics solutions that support multiple use cases are critical to sponsors that must quickly identify problems and discover those issues' root causes. To this end, sponsors require a centralized solution usable to view data trends on a large scale, throughout the trial, and granting a comprehensive view of single patients without the need to page through individual patient forms.

A FAST FLEXIBLE SOLUTION FOR DATA ANALYSIS

To help overcome sponsors' data access and analysis challenges, Revvity Signals leveraged the world-class TIBCO Spotfire® analytics platform to develop a set of powerful modules for performing common clinical trial processes. With a single integrated enterprise analytics platform, sponsors get a solution that supports every use case. The platform is fully customizable and can harmonize real-time access to data from multiple sources throughout all phases of clinical development.



Revvity Signals analytics platform, powered by global analytics leader TIBCO Spotfire®, provides a portfolio of purpose-built solutions that support sponsors throughout the entire clinical development process.

Additionally, Revvity Signals's clinical team can adapt these modules to answer almost any question, eliminating the need to invest in new solutions when new needs arise. For example, if new operational or medical questions arise, the solutions can be rapidly configured to pull in relevant data and display their results. The platform also offers a central place and consistent processes usable across varied studies and trial designs, meaning established workflows can be reused for multiple trials/therapy areas — saving time and money in development and validation efforts.

To improve data review workflows, Revvity Signals developed enhancements to the Spotfire platform that enable clinical teams to track or collaborate on data status directly within the analytics. Queries from electronic data capture systems can also be loaded into the solution to facilitate communication between study teams and data management. This important capability keeps trials on track by facilitating rapid data cleaning, ensuring data quality, and allowing quick identification of any missing or erroneous data.

SEEING THE PLATFORM IN ACTION

Revvity Signals's collaboration with Arcus Biosciences, a small biotechnology company focused primarily on cancer immunotherapies, represents one of numerous successful applications of our data analysis and visualization tools. Arcus Biosciences asked Revvity Signals to make its biometrics team more effective. They needed a universal, scalable, adaptable solution that could be used with flexible trial protocols and overlayed across vendors and systems. They also wanted to improve communication and collaboration among their teams, which were new and rapidly expanding.

In just three months, Revvity Signals mobilized a large team to work with Arcus Biosciences and implemented the clinical data review (CDR) module for five of its business-critical clinical trials. After seeing what was possible, Arcus began to ask new questions. The Revvity Signals team responded by working with individual study teams to refine the module and build in extra features that served each team's analytical and visualization needs. This fine-tuning included prior therapy, waterfall, and swimmer plots customized to specific therapeutic areas, as well as clin-ops dashboards that used Rave data. Revvity Signals, together with the Spotfire analytics platform, was able to answer analytics questions as fast as they could be asked.

The medical review module, which guides the user through common processes, including review of adverse events or abnormal lab results, was among the primary tools implemented. It allows data to be reviewed for all subjects, specific groups of study participants, or even single patients. It also allows the user to check off data that has been reviewed, which facilitates tracking and communicating progress with other stakeholders. Revvity Signals also provided tools for tumor response data visualization and study-specific visualization, as well as visit-level assessments.

Flexibility and speed were key to the success of Revvity Signals and Arcus Biosciences' partnership. Although the project began with a focus on clinical data review, Revvity Signals quickly switched gears when needs within Arcus Biosciences' operations became apparent. By implementing an operational effectiveness module, clinical operations and study management teams could easily see metrics related to sites, quality, speed, failures, and protocol deviations. Revvity Signals also offers modules for biomarker discovery and subject selection, ensuring safety and identifying key risks.

The Revvity Signals analytics solutions enhanced the Arcus Biosciences biometrics team's effectiveness by boosting collaboration among its various work groups and making it easier to communicate progress and findings with other company stakeholders. Quick access to data visualizations empowered them to answer a variety of study team questions and provided a way to triage ad hoc requests before a full workup or biometrics resources were needed. The company also used the new analytic tools to improve overall oversight of its data and vendors, as well as to quickly identify the root cause of several problems.

THE BENEFIT: TURNING DATA INTO INSIGHTS

While the Arcus Biosciences project focused mostly on clinical data review and operations, Revvity Signals can support sponsors throughout the clinical development process in areas such as risk-based monitoring, pharmacovigilance, and clinical operations. Capabilities such as line listing review are also critical for tracking progress and helping various trial teams work collaboratively.

Revvity Signals is a partner that can either integrate into your team or provide self-service analysis. Our expansive and customizable analytics platform allows users to work with many different data sources and create visuals that easily answer questions big and small. All the analysis tools can be quickly integrated with any data source: clinical trial management systems (CTMS), electronic data capture (EDC) systems, SAS, SDD, SAS/SHARE, electronic patient-reported outcome (ePRO) systems, and more. This enables sponsors to easily see relationships between disparate data, highlight actionable data, and track the status of data review.

Ultimately, sponsors want to protect patient safety and streamline clinical development so important treatments can reach the patients who need them faster. RevvitySignals's customizable analytics solution empowers sponsors to accomplish these goals. To learn more, contact us at https://revvitysignals.com/products/clinical-translational/clinical-solutions

ABOUT REVVITY SIGNALS

Revvity Signals, a division of Revvity, offers one of the most comprehensive suites of scientific software in the world. Our powerful informatics solutions are used across various industries, including Pharma and Biotech, Specialty and Agro-Chemicals, Energy and Petrochemicals, Flavors & Fragrances, Food & Beverage, and Electronics.

Revvity Signals Clinical solutions, powered by TIBCO Spotfire, provide a unified, scalable data analytics platform with unrivaled workflow flexibility to identify risks early, support dynamic collaboration, and safely bring therapies to market faster. From source to visualization to action, Revvity Signals Clinical solutions provide a holistic view across all your clinical data.

References:

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