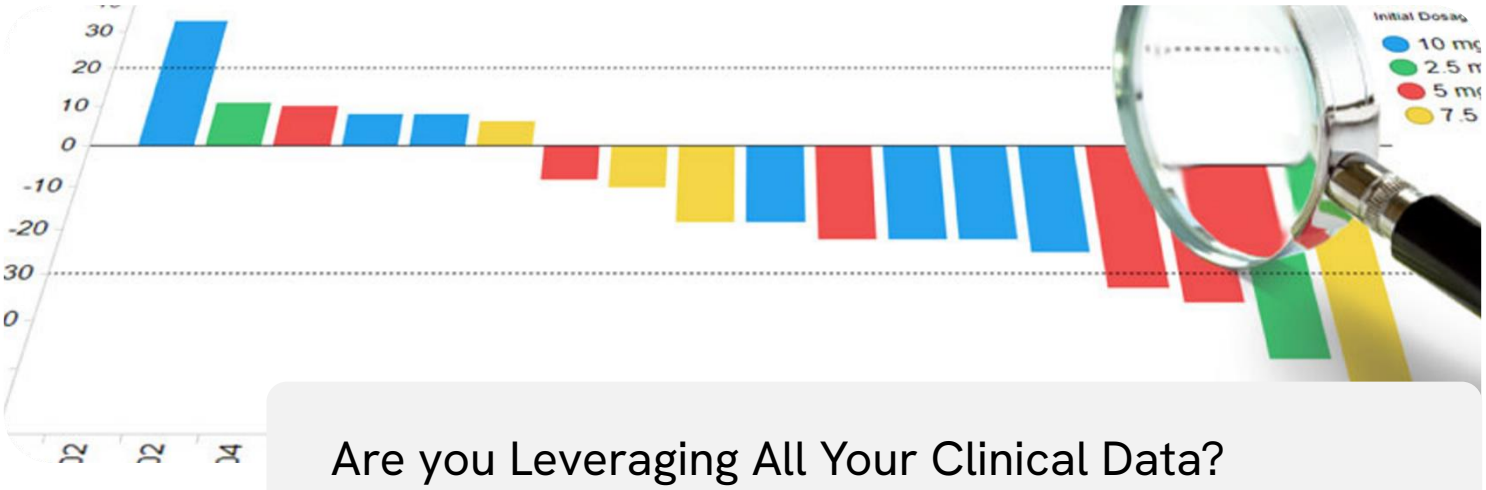

Are you Leveraging All Your Clinical Data?

To develop and execute a successful clinical strategy, trial sponsors must be able to acquire faster, more detailed data insights. To achieve new drug approval, trials must collect, combine, and analyze diverse data sets supporting operational, safety review, risk management, and other analyses crucial to drug development. Data aggregation, automation, and visualization not only accelerate trial data analysis but also illuminate insights hidden by traditional data review processes.

Integrating more data sources may provide even greater insights, such as combining efficacy data with pharmacokinetic and image information and potential stratifying information such as demographic, laboratory, and genomic data. This allows clinical study teams to understand therapeutic dose selection more fully, as well as the mechanism of action and target availability, to drive program strategy and decision-making.

Insights Through Advanced Analytics

In a recent webinar, experts from Revvity Informatics explored how advanced data aggregation and analytics using TIBCO Spotfire can help users visualize their data and achieve actionable insights. Speakers for the event included:

- Brent Meyers, Executive Director, Clinical Analytics, Revvity
- Philip Ross, Strategic Clinical Analytics, Revvity
- Don Sullivan, Principal Field Application Scientist, Revvity

Revvity Signals Clinical Analytics Solutions (Figure 1) represent an integral tool in helping biopharma companies and trial sponsors tackle data quality and collaboration challenges and enable more efficient better-managed studies. At its core, the value of aggregating distinct data sources in a time-relevant manner is in enabling more streamlined clinical development and better safeguarding of patients. Revvity Signals' customizable Clinical Analytics Solutions empower sponsors to accomplish these goals by affording users accelerated access to the clinical trial data they need to make swift, well-informed decisions.

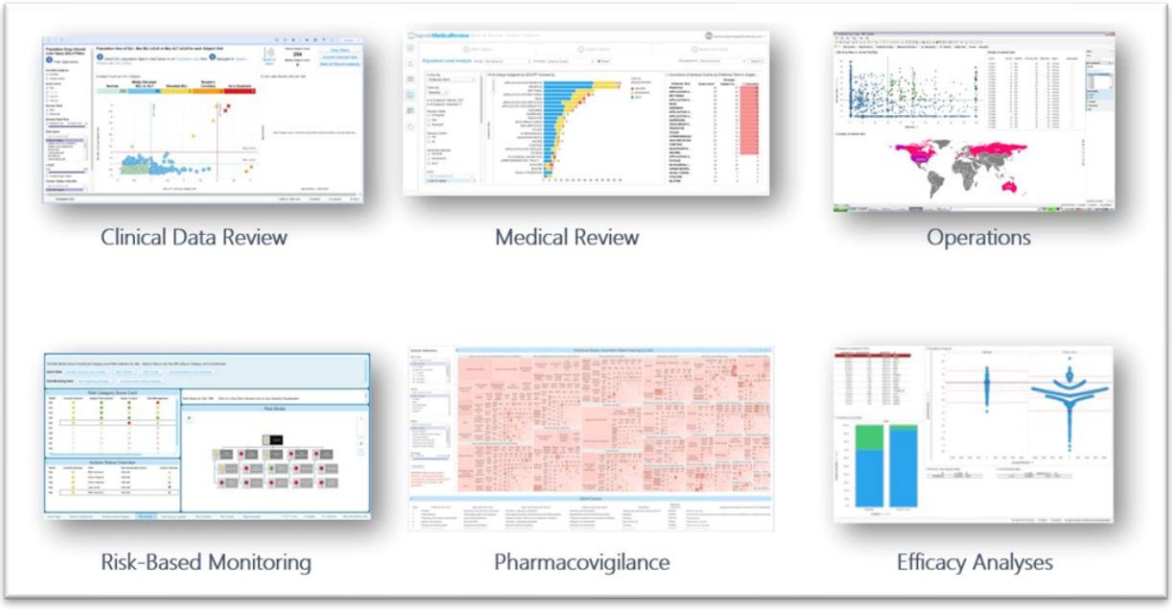

Figure 1. Clinical Analytics Solution modules are designed for fast and flexible access to clinical trial data for customizable trial analytics

Fast, Focused Data Review

Clinical analytics drives awareness of safety and efficacy data from ongoing, completed, or pooled trials. With Revvity Signals Clinical Data Review solution (Figure 2), one can explore safety and efficacy, underlying pathology, and patient characteristics.

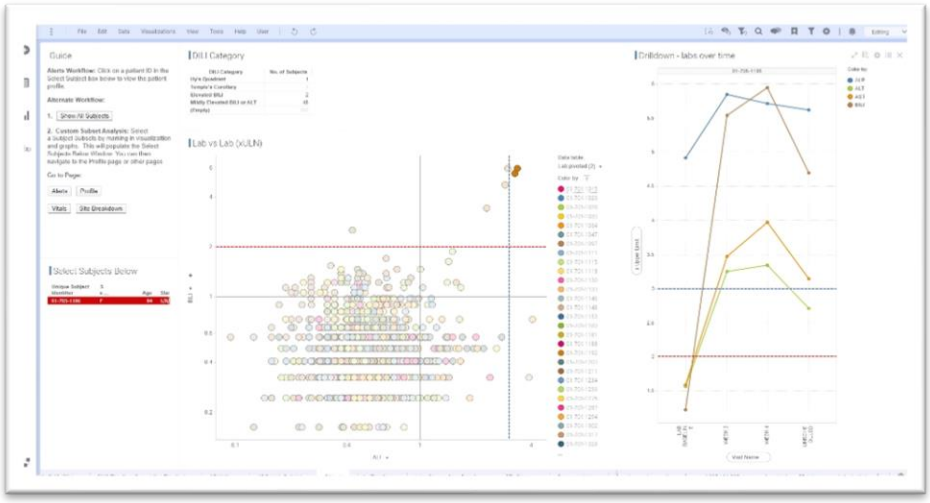

Figure 2. Clinical Data Review Solution provides a scientific exploration of the safety and efficacy of data.

These analytics can inform trial amendments or the design of upcoming trials, drive decision-making, and redirect new candidate discovery strategies. Additionally, these analytics are configurable to specific roles, studies, therapies, or trial designs. This enables relevant insights into each team's questions.

Equally important is to have an embedded capability with the analytics necessary to track data review processes and collaborate on insights across study teams.

Revvity Signals Signals Line Listing Review solution (Figure 3) allows clinical teams to evaluate emerging safety information, track the resolution of data questions, and collaborate with colleagues to protect patient safety and better manage data.

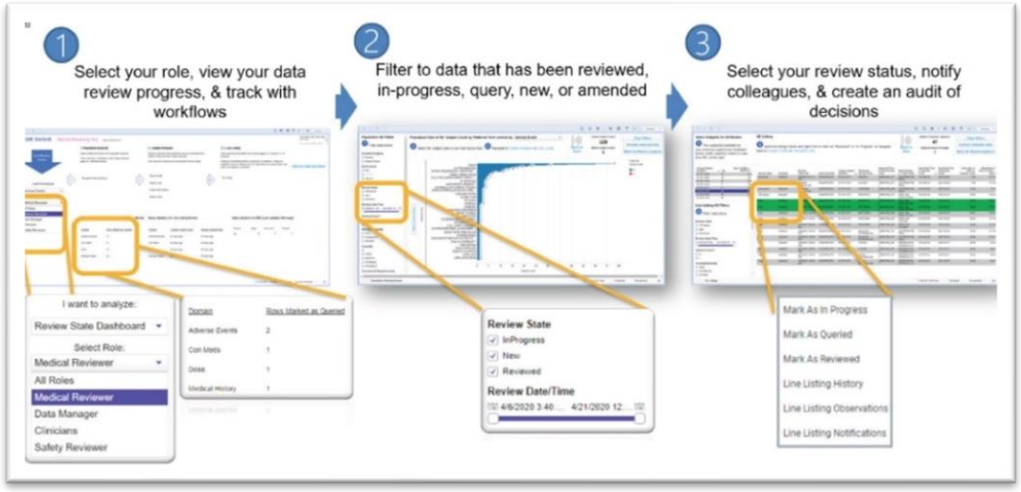

Figure 3. Signals Line Listing Review enables clinical teams to review, query, track and collaborate on their line listings to improve data quality.

Added Data Dimensions Drive Deeper Insights

Combining additional data sources with efficacy data provides fresh and powerful ways to gain further insights into therapeutic benefits and nuances of how different patients may respond to therapy. Identification of patient characteristics and how efficacy and safety may vary by the patient can inform therapeutic strategy for defining therapeutic regimes with improved safety and efficacy in different subsets of patients. Revvity's Clinical Analytics Solutions empower Clinicians to explore a variety of complex data domains at a more granular level to increase clinical understanding of drug action and effectiveness.

Pharmacokinetic and Pharmacodynamic (PKPD) Data

PKPD data is an example of additional data relevant to drug exposure in clinical trial analytics. These data include single-dose exposure information with estimates for Cmax, Tmax, Cmin, and Area Under the Curve (AUC) (Figure 4).

Multiple dose trial data similarly provides estimates for Cmax, Ctrough, and AUC that establish how patients respond to multiple treatment doses (Figure 5). One or more of these parameters may need to be analyzed in plots that correlate the PKPD parameter with safety and efficacy data to define the most appropriate estimate of a treatment's toxicity, efficacy, and therapeutic index. Revvity's powerful Clinical Analytics Solutions automate the aggregation of PKPD data into visualizations that refresh as new data is generated that drive rapid dose selection and other clinical trial decisions.

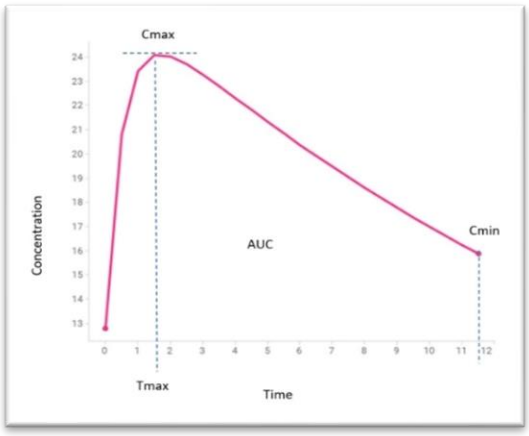

Figure 4. Single-dose pharmacokinetics

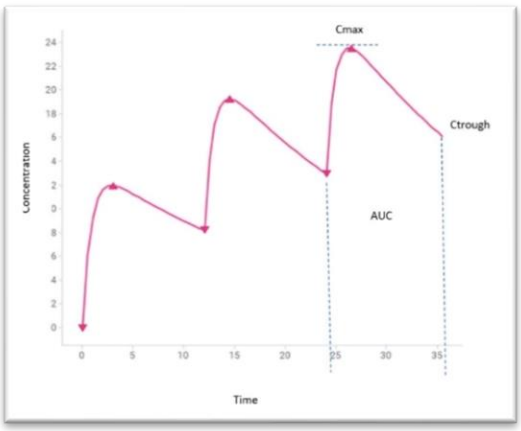

Figure 4. Multiple-dose pharmacokinetics

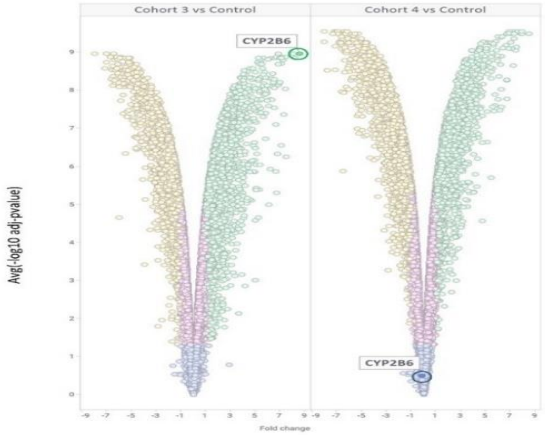

Figure 5. Volcano plot of differential expression for patient cohorts

Other visualization examples of PKPD data are exposure-response curves, which reveal the exposure required to achieve different response levels in patients. In Figure 6, we see that the AUC resulting from treatment must achieve a sufficient level to deliver a higher range of treatment responses. These curves drive dose selection in preparation for additional clinical trials to ensure that a sufficient treatment level, route, and frequency are chosen to ensure expected efficacy while improved understanding of treatment exposure and response will help confirm the drug's mechanism of action, drug availability and exposure, and target engagement to build confidence in the treatment rationale. Clinical analytics accelerate access to PDPD parameters and automates the analysis of correlations between these parameters and clinical safety and efficacy measures.

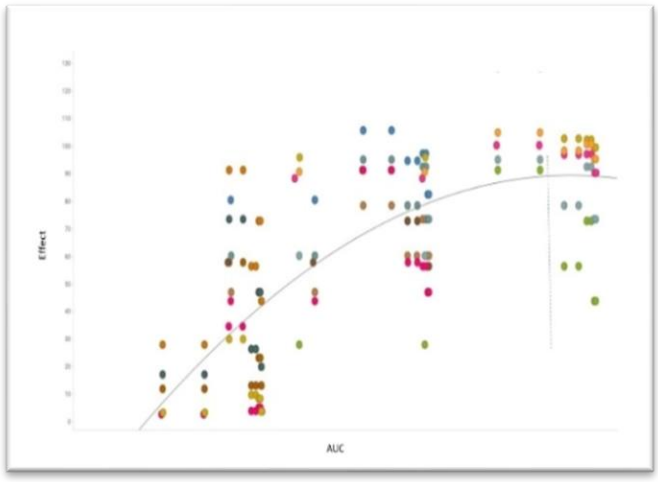

Figure 6. Exposure-response curve (AUC and Effect)

Pharmacogenomic Data

Accessing and aggregating pharmacogenomic information about patient mutations can inform further details of patient responses to treatment. In Figure 7, we see that 80% drug response is achieved at a lower dose (100 mg, for example) in patients with lower liver drug metabolism. In contrast, the same response requires a higher dose (150 mg, for example) to achieve 80% drug response in patients with a liver enzyme mutation leading to higher drug metabolism. This type of information can be useful in informing dose selection.

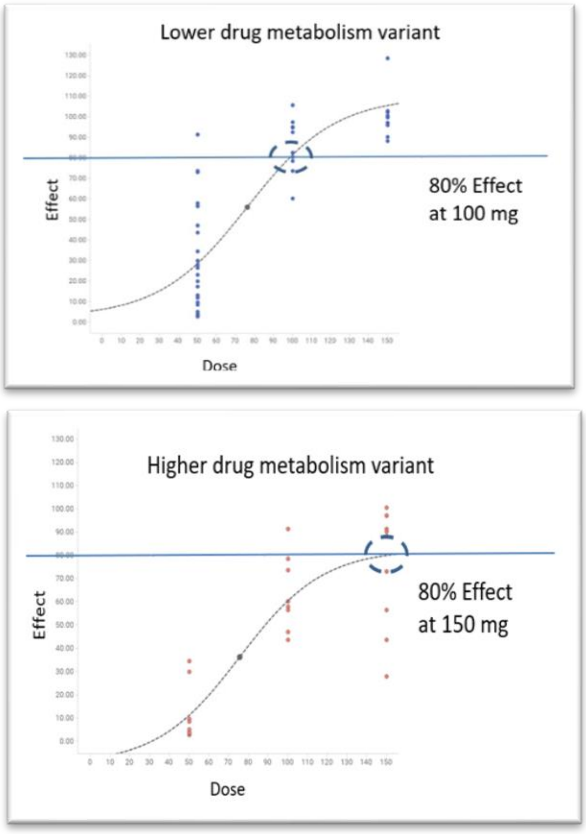

Figure 7. Dose-response curve (dose and effect) for patients with different mutation variants (a & b)

Differential expression information can further inform expectations for patient responsiveness to treatment. In Figure 8, we see that cohort 3 has higher expression of a liver enzyme, for example, with little or no increase in expression of that enzyme in cohort 4.

Survival plots are another analytic that can inform understanding of treatment responses. The ability to separate the survival of a patient group can indicate improvement in treatment response. Figure 9 shows an example of 3 survival plots representing three gene expression levels and their corresponding patient survival probability over time.

Access to the Right Data at the Right Time

Clinical data analytics depend upon having the right data accessed in a timely way, aggregated in a useful manner, and with an effective analytic to detect a useful treatment response. Added data domains, like PKPD and pharmacogenomic, can be readily integrated into powerful visualizations that provide another dimension to clinical decision-making.

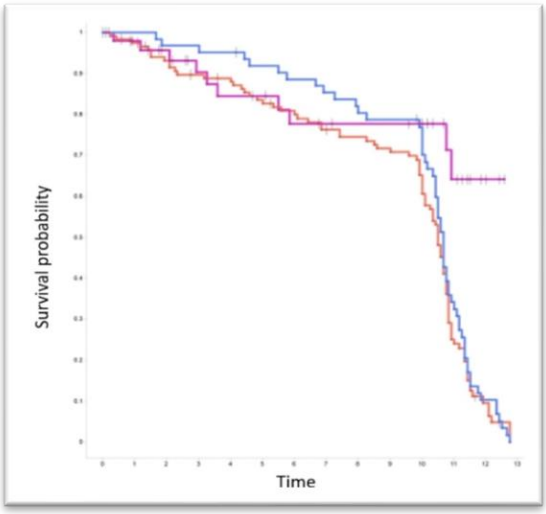

Figure 9. Survival curves for patient groups having different gene expression.

Revvity Signals Clinical Solutions are fast and flexible analytics that drive clinical insights in customizable ways to maximize the value and development of treatments, providing clinical study teams:

- Access to time-relevant data for faster decision-making
- Powerful visualizations and analytics for deeper insights across all study data
- Customizable workflows to support dynamic, cross-functional collaboration
- Modular, agile and configurable solutions for any clinical analysis use case
- Connection to a variety of data sources
- Rapid deployment - in weeks versus months
- Flexible deployment options for self-service, full-service, or both

The Revvity Signals team, in partnership with your clinical team, can tailor these solutions to suit your trial's unique needs and growth to maximize the impact of the analytics on your clinical decision-making.

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