SOLUTION OVERVIEW

Clinical Data Review Analytics Solution

revvity signals

Anyone involved in clinical trials knows that the pace of data generation, and the complexity and volume of the data produced, has exceeded the capabilities of most existing informatics solutions. Medical monitors, safety review teams, biostatisticians, data managers, pharmacologists, and others working with clinical data need interactive solutions that enable real-time analysis and faster decision making.

Real-Time Analysis

Data challenges in clinical trials affect everyone from the frontline data reviewers to the VP of R&D to the patients themselves. Working with static reports, scrubbing data, or waiting for another group to deliver reports, delays decisions and impedes the ability to quickly – in real time – detect issues with data quality or unexpected safety signals. This risks submissions being delayed or rejected, or even market withdrawals.

An effective solution must let must let reviewers act on questions, uncover trends, and identify risks by giving them the ability to interact in near real time with a wide variety of data sources to make the most effective decisions about safety and efficacy.

Market Trends Affecting Data

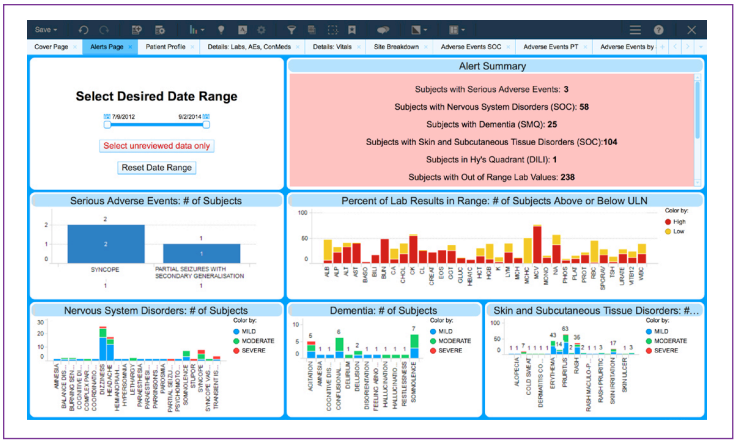
What's driving the data deluge in clinical trials? There are a number of market trends impacting data:

- Advent of precision medicine and value-based treatment schemes
- Rising use of real-world data to show safety and efficacy beyond randomized clinical trials
- Growing complexity of scientific questions and content
- Increasingly distributed R&D and data exchange among stakeholders
- Rapid cloud and mobile adoption
- Explosion of device data
- Data from these fragmented sources must be effectively aggregated, and the content analyzed, to leverage hidden insights.

At a Glance

The Revvity Clinical Data Review Solution provides the most effective way to perform instream review of study data, empowering clinical development teams to make smarter decisions faster.

- **Allows merging of data** across domains in an easy to use visual environment where medical monitors, safety review teams, biostatisticians, data managers, pharmacologists and others can easily identify safety issues/signals, then investigate subject profiles across data domains.
- **Offers Alert Workflow:** Users can set up alert criteria based on patient safety, efficacy and medical outcomes.
- **Enables Ad Hoc Workflow:** Users can investigate study level data to identify patients of interest, create custom groups of patient on the fly and drill down to the cross-domain profiles.
- **Empowers team** to link to individual patient narratives.
- **Includes Line Listing Review:** Monitors can mark line listings as read or reviewed, and are notified if line listings are amended. An audit trail is available for the review process including reviewer name and date.



Clinical Data Review alerts page

In-stream Review

The solution to these challenges lies in dynamic in-stream review of study data. Revvity's Clinical Data Review solution empowers clinical development teams to make smarter decisions faster by providing a 360-degree, real-time view into patient profiles, adverse events, and all relevant safety domains, using a common set of analysis capabilities.

Built on Spotfire® analytics and visualization software, the Revvity's Clinical Data Review automatically combines data to allow clinical development team members to interactively explore information and discover new relationships. With the ability to quickly visualize and analyze data, team members can optimize the clinical trial process and focus their efforts on obtaining the insights and answers ***v***they need to bring drugs and devices to market faster.

Faster to Submission

The Clinical Data Review solution is proven to accelerate the clinical data review process, driving down time, process steps, and costs.

- Reduction in days-per-month-per-trial for medical data review – 2-5 days
- Reduction in ad hoc report requests to biostats team – 20-40 percent
- Reduction in time to database lock – 10-30 percent
- Reduction in database unlocks – up to 50 percent
- Reduction in IT infrastructure and support costs – up to 67 percent

With in-stream data review using the Clinical Data Review solution, clinical teams get submission-ready faster and reduce the likelihood of submissions being rejected or the potential for market withdrawal.

Get Submission Ready Faster

Clinical Data Review lets users set up actionable alerts in personaguided workflows based on industry best-practice data views. It provides intuitive, dynamic visualizations that are powered by validated statistical models. Pre-built data connectors and data services deliver on-demand access to any clinical data source.

Reduce Likelihood of a Rejected Submission or Market Withdrawel

The likelihood of problems with a submission decrease significantly due to a 360-degree view for all relevant CDISC domains across a clinical program, and a full audit trail on activities related to GCP decisions. Medical review collaborations across partnering organizations are better monitored with a vendor oversight dashboard.

Optimize Your Data Processes

Data provisioning, aggregation, and review are optimized by a single, unified data analytics solution – from source to visualization to action. Data mashups can visualize content from multiple sources in a secure, regulatory-compliant solution deployed either on-premises or in the cloud.

Revvity's Clinical Data Review, with in-stream review of data aggregated across domains, ensures optimal decision making on safety and efficacy, early in the clinical data review process.

Dynamic Hy's law visualization to quickly identify subjects with possible drug-induced liver injury.

Revvity provides a one stop shop for clinical data insights including clinical data review, risk-based monitoring, drug safety, and clinical operations. Revvity is the exclusive distributor of Spotfire® for life sciences companies world-wide. Spotfire® is used by 23 of the 25 largest pharmaceutical and biotech companies and ten of the top 15 clinical research organizations to draw insights from clinical data. Customers benefit by accessing the Spotfire® superior technology coupled with Revvity's deep domain knowledge and intellectual property. Because many Life Sciences R&D organizations have already adopted Spotfire®, those organizations can easily embed Revvity's clinical solutions into their existing analytics infrastructure and processes.

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