WHITE PAPER

Powering More Efficient Clinical Development with AI and ML

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Clinical trials often include multiple, complex data sources so the ability to effectively manage and unify these disparate data sets for exploratory analysis can make or break the effort to bring a new drug to market. Successful drug development requires near real-time access to data to allow clinical researchers to rapidly understand trial data and address issues quickly to keep the trial progressing. These data insights, which can point to the ongoing success, data quality, and safety of a clinical trial are also, conversely, vitally important to inform if—and when—a clinical study should be halted. Further, providing a framework to develop and execute a nimble clinical study requires collaboration among clinical data managers, data scientists, medical reviewers, and others at the sponsoring company.

Considering the resources needed to manage data quality and safety review during clinical studies, and the increasing costs of drug development, it's imperative to have an intelligent infrastructure that allows for faster, more timely data analysis. Such an infrastructure makes real the ability to "fail early, fail fast," thus saving investments for the most promising programs.

The volume, importance, and complexity of the data generated from clinical trials make clinical data a natural fit for the use of artificial intelligence (AI) and machine learning (ML) tools. When applied appropriately, AI/ML applications can help to intelligently automate the collection and cleaning of data, aid data mapping, and perform advanced analytics to unlock hidden insights, all while providing a unified solution that improves clinical development workflows and fosters stakeholder collaboration.

Improving Clinical Data Management

In today's clinical development landscape, access to the most recent data is paramount for leveraging AI/ML tools to improve the safety, efficacy, and reproducibility of clinical trials. Leveraging the cloud, clinical researchers today can automate uploading near real-time clinical data to build a robust, centralized data repository.

It's no secret that data from multiple sources can be messy and that accurately mapping these disparate data sets is time-consuming yet critical for downstream analysis. Revvity Signals has built a patented, proof-of-concept ML-based automated mapping engine that can map EDC data against the study data tabulation model (SDTM) more quickly and accurately than manual processes. The auto mapper leverages existing, manually created maps for the engine to recognize forms and perceived structures to recommend mapping and transformation of data.

Users can upload a source dataset, choose a target standard and, with a single click, the ML engine transforms the data and displays the predicted schema mapping. Using intelligent, human-in-the-loop automation, a human user reviews the mapping and, if not satisfied with the results, can manually adjust the mappings to provide quick

corrections. Once satisfied with the mapping, the user saves it and moves to a page where they can view the predicted transformations. Here, again, the user maintains control and can choose whether to use the ML-generated predicted transformation or to provide their own transformation. As an example, if the dates are not parsed properly in their column, the user can provide information to allow the system to read the dates correctly. If the predicted transformations are discarded, the system can validate the new formats provided by the user against the source data to ensure this feature is foolproof.

Having tested this method of automatically mapping data using machine learning, while allowing for human review, Revvity Signals demonstrated that it provides a faster way to map data and, more importantly, reduces errors, while facilitating near real-time access to trial data.

AI-Driven Data Insights

Many biopharmaceutical companies use Spotfire® in clinical trials for a variety of applications such as clinical data review, medical review, risk-based monitoring, and operational metrics, among others. Revvity Signals is the exclusive channel partner for Spotfire in clinical development. Spotfire has released the Spotfire Copilot™ AI assistant, a natural language extension to the platform that leverages large language models (LLMs) to aid in querying data and to generate charts and graphs for data visualization.

Using trial data, augmented with other internal data or proprietary documentation, the Spotfire Copilot is aided by retrieval augmented generation, an approach that improves the effectiveness of an LLM by using internal data as context for the LLM's answers to specific questions. This allows users to index the content generated from these tools alongside their existing data to unlock fresh insights.

Querying adverse event (AE) data is one such application for these tools. For instance, a trial manager could ask a simple question to describe the information contained in the AE table and how it could be used. Spotfire Copilot uses some of the information from the Spotfire session and in combination with the LLM, examines the data, to provide a real language description of what the data contains. In this case, it would return a detailed description of the types of data found in the data columns, subject identifiers, sponsor identifiers, as well as how these data might be used. This could suggest, for example, how a user could take these data for a temporal analysis of AEs over the course of the study to uncover trends not previously detected that may require action with one, a few, or all of the trial sites to manage these events.

In addition, again using a simple query, Spotfire Copilot can generate visualizations to help users better understand what the data represents. Perhaps a trial manager is interested in the racial breakdown of a trial and AEs. Using the same tools and the data at hand, the AI assistant would generate a graph based on the query.

In addition, building on that session, a user can ask Spotfire Copilot to provide highlights, trends, and outliers contained in the visualization. For instance, it might answer that it detected the presence of severe cases in the neoplasm category in both the high-dose and low-dose treatment arms. This could send the researcher back to the

chart to drill deeper into the data—down to the individual patient level if needed—to determine the causes and severity to help decide how to address these AEs. In a trial where these AEs were relatively few, a user might miss these cases without the aid of AI. But the AI assistant, in conjunction with the LLM, uncovered important information that might have been overlooked simply by examining the chart.

Enabling Persona-Driven Workflows and Collaboration

Further empowering AI/ML tools in drug development is the Signals™ Clinical solution from Revvity Signals that enables real-time data access, robust self-service analytics, and traceable decisions. Signals Clinical drives traceable decisions directly within your visualizations and workflows. Using Signals Clinical, you can create notes, highlight data issues, or even submit queries in line with your analyses. Signals Clinical provides a unified record of decisions in a centralized, collaborative solution.

signalsClinical

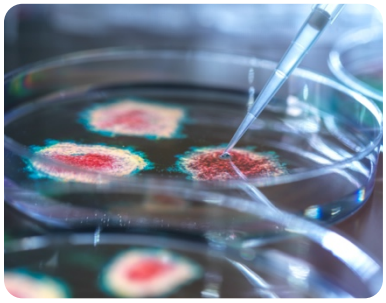
Signals Clinical connects to various data sources, imports data on the schedule users determine – perhaps daily – and then helps to unify the data consistently each time. The analysis-ready data can easily be used to produce insights that aid understanding of the data.

Medical reviewers, data managers, clinical researchers, and operations managers all examine clinical trial data differently according to their role. Signals Clinical can be configured to automatically provide individualized access to and custom views of the data a user needs based on their role in the trial. Supporting clinical workflows based on individual roles ensures that users can efficiently access the data they need, gain insights, submit and track data queries, and even receive alerts to new data that may need immediate attention.

AI plays a part for many of these roles. For instance, the data manager is responsible for query management, data cleaning, and resolution of queries. AI can assist in data review and cleaning of the clinical study data. In the same vein, the medical reviewer accesses data to perhaps monitor AEs, evaluate treatment efficacy, or conduct an exploratory medical review—tasks that can be facilitated using AI.

Signals Clinical helps foster collaboration across different clinical development roles and provides a unified record of clinical trial decisions so all stakeholders are fully informed. This allows clinical researchers to manage their workflows around shared tasks by tracking data review, tagging data and recording decisions, and submitting queries to EDC.

Commitment to AI/ML Tools in Clinical Development



At Revvity Signals, we are committed to continuously improving data access, analytics, and decisions in clinical development, including innovative uses of AI/ML. By delivering near real-time access to trial data, robust self-service analytics, and traceable decisions, our native SaaS solutions like Signals Clinical create more collaborative, focused, and efficient clinical trials, while advanced AI/ML tools provide hard-to-find insights and intelligent automation of repetitive tasks that can potentially reveal critical insights from your data that may have otherwise gone unnoticed.

Revvity Solutions ensures that your clinical data is AI-ready and optimized to unlock its full potential, fueling insights that can streamline clinical development.

For more information on how Signals Clinical and Spotfire Copilot can power the incorporation of AI into your clinical trials, visit us here

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