PREVAIL INFOWORKS

Customer Case Study

Advanced Insight into Live Study Data Supports Shortened Development Cycle and Expedited Rolling NDA Submission

Early observations across clinical and operational data helps innovative pharmaceutical company accelerate development timelines by months and reduce trial costs by millions of dollars

OVERVIEW

Customer Profile

North American pharmaceutical company, focused on auto-immune disease

Customer Challenge

Phase II dose-escalation study for a challenging therapeutic indication, requiring frequent and rapid turnaround with DSMB

Solution

Prevail's unique analytics leveraging existing data sources and set up in just four weeks

Key Customer Outcomes

Higher quality data was credited with the FDA accepting the Phase II study as a pivotal study, saving $20 million in development costs and further reducing project timelines

Patient narratives for a rolling NDA submission made easier through auto-generated patient profiles, saving weeks of time

Discovered during the study an unlooked-for and promising new therapeutic indication in study data, which is now in a Phase II trial

KEY STATS

Savings of

$20M

Timeline Reduced By

9 Months

Clinical trials are producing ever-growing volumes of clinical and operational data, at greater velocity and from more sources. As a result, trial sponsors and CROs are struggling just to foresee and avoid study problems – much less to effectively utilize data to improve study efficiency, data integrity, and outcomes.

Prevail's customers know it doesn't have to be this way. Leading pharmaceutical companies, biotechs, and CROs are leveraging Prevail's innovative tools to gain practical insights into live studies, regardless of protocol, data, and system complexity.

Customer Challenge: Managing a Complex Study for a Highly Challenging Indication

An innovative North American pharmaceutical company focused on auto-immune disease was attempting to succeed where large pharmaceutical companies had failed. The company had a promising therapy in a challenging therapeutic indication – one which had already seen more than 30 drugs tried and failed by other sponsors.

Our customer had begun a Phase II dose-escalation study which required detailed and frequent reporting to a DSMB to get permission to dose escalate. However, the company was relying on highly experienced researchers to do this manually, which was extremely time-consuming, risked data quality, and was taking a talented research team away from higher-value work on the study such as assessing progress towards study endpoints.

The Solution: Prevail's Unique Software-as-a-Service Technology

Recognizing that gathering quality data more quickly – in a manner lending itself to faster and more unified analysis – was critical to the study's success, the company began looking for a better solution.

Following an evaluation of multiple vendors (including ones it worked with previously), the pharmaceutical company chose Prevail's innovative solution for several reasons:

> **"Prevail offers a methodology for understanding your data better. We all see data but we rarely understand what it really means. You have better signal-to-noise ratio. You get rid of the garbage. You have a better understanding of what the drug does in that indication. That actually helps the FDA understand the risk to benefit ratio."**
>
> Vice President of Clinical Affairs, North American Pharmaceutical Company

Empowers Research Teams with Advanced Visibility to Live Studies

- Provides a single, unified view with detailed reporting, analytics, and visualizations encompassing clinical and operational data within and across studies – from all data sources including EDC, CTMS, labs, imaging, ECG, safety, IRT, ePRO and more
- Offers early observations with access to live study data, without breaking the blind or requiring alpha-spending
- Delivers direct access to analytics and visualization tools for clinical researchers, aligned with a company's business processes and without requiring IT or programming involvement – allowing researchers to apply their experience to adjust data parameters on the fly and see the results immediately

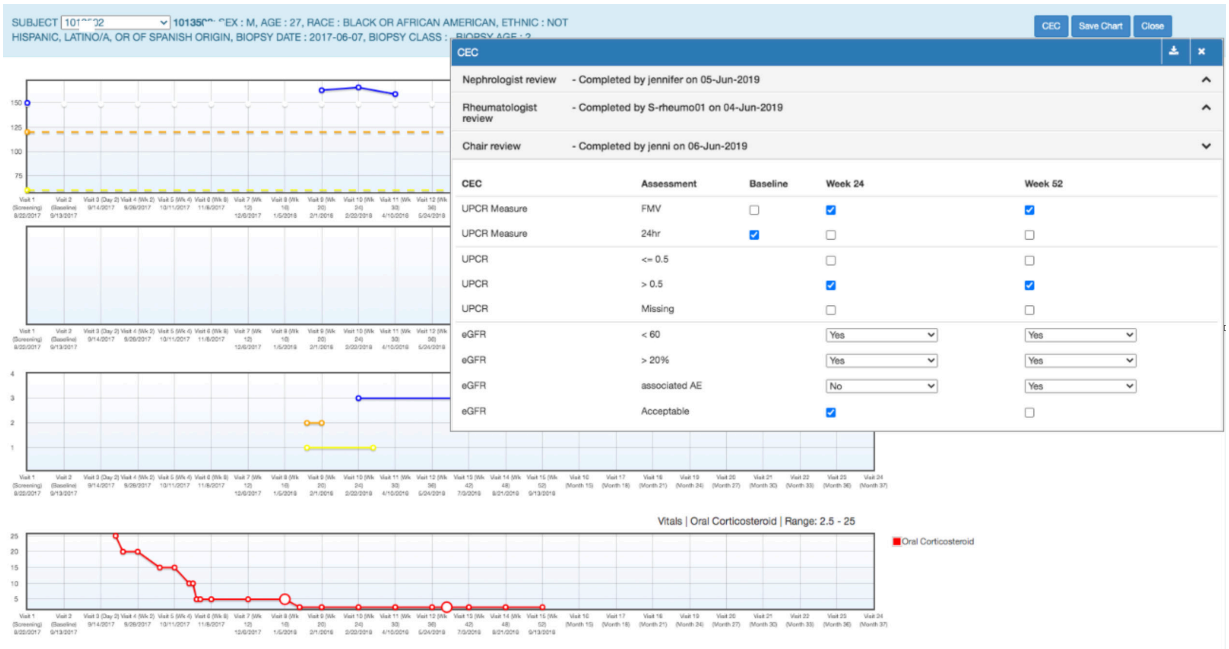
Delivers Rapid Time-to Value from Automated, System-Agnostic Data Extraction

- Overlays and integrates data from any existing internal systems as well as external ones provided by CROs and other service providers, in any format (e.g. not only SAS)
- Fully automates the data extraction process, independent of whether a system supports APIs or SFTPs
- Provided as Software-as-a-Service (SaaS) model that can be set up by Prevail in 4-6 weeks, regardless of system and study complexity

Customer Results: Phase II Success Exceeding All Expectations

After the company chose Prevail as the best fit for its demanding research and data requirements, we got to work. We were able to set up our solution and automate data integration from multiple systems in just four weeks - while the study was underway.

Results exceeded our customer's most optimistic expectations, freeing their clinical research team from time-consuming manual effort and providing them with tools to gain unique insights from the study data.



Prevail helped our customer reduce development timelines by months, and study costs by millions of dollars through our unique ability to combine a unified view of a study encompassing all clinical and operational data sources with workflow tools. As just one example, the Clinical Endpoint Committee tool shown here allowed adjudication committee members to easily review all of the relevant data points and complete a centralized electronic adjudication form.

The company itself has credited Prevail with the following benefits:

- The phase II study met its endpoints and was accepted as a pivotal study by the FDA based in part on the quality of the data, allowing the company to conduct a single Phase III study instead of the usual two – saving months of effort and an estimated $20 million in development costs.

- The rolling submission time of the company's New Drug Application was accelerated by weeks and the cost and effort reduced because all of the patient profiles (containing all study data collected for an individual patient organized by time) and other data needed for the required patient narratives were auto-generated from Prevail's system.
- During the Phase II study, the clinical research team discovered an unlooked-for and promising new drug indication in the data. This allowed the company to accelerate into a Phase II study by leveraging the body of work in the other indication for the same molecule.

211 N 13th Street
Philadelphia, PA 19107
+1 267.797.2001
www.prevailinfoworks.com

About Prevail InfoWorks

Prevail is a pioneering life sciences software company with a unique combination of clinical expertise and engineering prowess. Our innovative and patented technology quickly and easily integrates, normalizes, reconciles, and presents aggregated data, analysis, trends, and metrics encompassing all study-related data sources through a single interface - making clinical development faster and easier, while reducing trial risk. With Prevail, trial sponsors and CROs can obtain unmatched, real-time answers to virtually any clinical, operational, and financial question regarding a study or program.