

Biotech Delivers a Superior Patient and Site Experience with the Medidata Platform

The Challenge: Become the Sponsor of Choice for Patients and Sites

Patient recruitment and retention is a challenge in clinical research—especially in ultra-rare orphan diseases with a limited number of patients and several competing trials. “To become the sponsor of choice for sites treating patients with congenital hyperinsulinism (CHI), we needed to deliver a superior patient and site experience,” says Erin O’Boyle, head of clinical operations for Rezolute.

As a small biotech company with a five-person clinical operations team, Rezolute needed to make the best use of limited funds and time. “Our team’s past experience with database integrations, multiple passwords, lack of visibility, and unknown protocol deviations convinced us that we needed a unified platform with one URL,” O’Boyle says.

The Solution: Medidata Platform

After evaluating other technology platforms, Rezolute selected the Medidata Platform. “Medidata’s industry leadership, end-to-end solutions, and flexible platform make it a great fit for a small startup,” says O’Boyle. For a faster study launch, Medidata’s team of experts advised implementing Rave EDC and eCOA first. Rezolute soon added RTSM (Randomization and Trial Supply Management), Site Payments, Safety Gateway, and Coder.

Avoiding the complexity of working with multiple vendors significantly reduced startup time. “Regulatory and site approvals are faster with Medidata’s unified platform, and so is site training,” O’Boyle says.

“Visibility into patient reporting helps us mitigate protocol compliance issues early in the study rather than later, when it’s harder.”

Erin O’Boyle
Head of Clinical Operations, Rezolute

Value

- Reduced study startup time
- Improved study compliance
- Delivered a superior patient and site experience
- Streamlined communication between all trial stakeholders
- Allowed sponsor to focus on core tasks rather than managing multiple vendors

Improved Study Compliance and Transparency

With one URL and one login, the clinical operations team can view real-time study metrics, team performance, and patient-reported data. “Visibility into patient reporting helps us mitigate protocol compliance issues early in the study rather than addressing them later, when it’s harder,” O’Boyle says. “For ultra-rare pediatric diseases, we’ll often open one country for one patient. You don’t get a second chance, so getting it right the first time is critical.”

Superior Patient and Site Experience

Rezolute simplified the patient experience and improved data quality with eCOA. Patients view and enter data on one easy-to-use interface and are even sent automated reminders. “Just managing day-to-day life is difficult enough for our patients without having to remember to record data four or more times a day,” O’Boyle says. “Patients appreciate the reminders, and they improve compliance.”

The Medidata Platform also simplifies the site experience, making Rezolute an attractive sponsor. With one URL and one login for all study activities, sites significantly reduce their training requirements and can quickly access critical patient and study information.

Sites also appreciate the streamlined payments process. With Site Payments, tasks completed in Rave EDC instantly trigger payments for visits and procedures, significantly improving site satisfaction. Rezolute pays sites in 30 days instead of the 90 days typical in the industry. “It says a lot to sites when a sponsor sends out payment the month after a site initiation visit,” says O’Boyle.

Streamlined Communications

Communication is often the greatest success or failure in a clinical study, according to O’Boyle. “With the Medidata Platform, we have a unified environment for reporting accurate data, reviewing data, and reporting accurate study results,” she says. “It streamlines the study process for everyone involved—our team, sites, and patients.”

By working on a single unified platform, Rezolute met its goals to improve study compliance and transparency, streamline communication, and deliver a superior clinical trial experience to become the sponsor of choice for patients and sites.

About Rezolute

Rezolute is a small biotech company advancing targeted therapies for rare, metabolic, and life-threatening diseases. Its lead clinical asset, RZ358, was found to be effective in a Phase 2b trial as a potential treatment for congenital hyperinsulinism (CHI), an ultra-rare pediatric endocrine disorder.