Reata Saves Millions Leveraging the Adaptive Functionality of Medidata Balance®

The Challenge

Reata Pharmaceuticals, Inc. is a privately held company located in Irving, Texas dedicated to researching and developing breakthrough medicines for difficult-to-treat diseases with significant unmet needs. Embarking on a new cardiovascular Phase-II clinical study with multiple study objectives, Reata was challenged with finding a randomization and trial supply management (RTSM) solution that would accommodate the study's highly adaptive trial design and detailed protocol.

Many of the trial's characteristics pertaining to patient randomization and drug assignment could not be specified during the study build. Reata wanted to accommodate dosing (escalations, reductions) and cohort size changes during the course of the trial based on accrued in-study data. With this level of complexity, finding the right solution was critical to the success of the trial.

Having extensive eClinical experience, the senior manager of bioinformatics at Reata was not confident that a traditional interactive voice or web response (IVR/IWR) system could meet their RTSM needs. The study had a level of complexity that prompted Reata to look outside the traditional IVR vendors and solutions that were not sophisticated enough to handle such a complex and evolving study design. The other vendor solutions evaluated were not developed to support an adaptive trial design without expensive and time-consuming programming—neither of which was acceptable to Reata.

The Solution

Reata identified Medidata Balance—a new generation of cloud-based RTSM that supports robust treatment design, including rule-based dosing and titration—as the only unified RTSM solution that would support a trial of this complexity. The solution provided agile functionality to support dose escalation as well as the ability to quickly and easily drop a study arm.

Key Outcomes

- Condensed three studies into one, significantly reducing study costs
- Completed study setup in only two days, reducing the startup timeline as well as the overall study duration
- Performed real-time, mid-study changes without vendor intervention—providing agility and control

About Balance RTSM

Medidata Balance heralds a new generation of cloud-based RTSM capabilities including:

- Unparalleled agility and control for project sponsors and CROs
- New user paradigm based on an easy, 100 percent configurable interface
- Choice of deployment options; unified with Rave EDC or standalone solution
- Best of cloud-based, agile technology to streamline design and provide real-time visibility into operations

Traditional IVR/IWR systems were designed to address static, pre-defined requirements. Medidata Balance not only handles pre-defined requirements but also enables changing requirements to be implemented quickly and easily resulting in greater flexibility in today's adaptive environment. Now prototypes can be established in hours, setup can be completed in weeks and an arm can be removed mid-study without the need for a vendor change order. Tightly integrated controls accompany this flexibility to ensure all changes are authorized and tracked. Balance manages the most challenging treatment and supply requirements even in complex adaptive studies.

Additional benefits that drove Reata to select Balance included the following:

- The Medidata Clinical Cloud® provided real-time visibility to RTSM transactions and rapid turnaround to form completion. Reata used Medidata's cloud-based technology for electronic data capture (EDC) and management (Medidata Rave®) for their other studies, so adding Balance provided all of the additional benefits of the unified EDC/RTSM solution—including facilitating a positive patient experience. This was an incredibly important factor to the sponsor, as the Phase-II trial's small subject population added additional pressure to ensure enrollment and patient experience was efficient and error-free to minimize the dropout rate. This was achieved.
- Balance was the only 100 percent configurable solution available. Because no pre-programming was needed, study setup and in-study modifications were fast and easy—making it the obvious choice.
- Balance's unification with Rave enabled Reata to use the same interface for entering patient data and receiving randomization and dispensation instructions—offering unparalleled agility and control. Balance's stratification and dosing capabilities were two major benefits for interacting with this particular build with Balance. Balance held the randomization factor data and the parameters for each particular patient, and the form was visible to the sponsor but was inaccessible by the site maintaining the blind.

"We were using an IVR system that was inflexible and a patchwork technology," said Arthur Gibson, III, AVP of Bioinformatics at Reata Pharmaceuticals. "The more we understood the system, the clearer it became that it was not a good fit for us. We needed a system that not only accommodated our needs but also could be easily modified during the course of the trial. We found that system in Medidata. Their randomization and trial supply functionality presents a unified solution with Rave so everything works together seamlessly. Balance is a 'best-in-class' solution that did not financially constrain us."

The Impact

The benefits Balance has brought to Reata's business cannot be overstated. Medidata's platform enabled Reata to move forward with an adaptive trial design and combine three studies into one. The highly powerful and configurable system also allowed Reata to adjust to various dosing schemes while maintaining the study blind. By adopting Balance into its R&D processes, Reata saw significant value on an accelerated timeline in the areas of:

- **Cost**
  Using an adaptive trial design allowed Reata to assess dosing during the course of the trial, giving the advantage of not having to run a separate dosing study. Rather than conducting three separate studies and waiting for the outcome of each before moving forward, Reata was able to combine three studies into one at considerable time and cost savings—estimating the savings of each trial to be in the millions.

About Reata

Founded in 2002, Reata Pharmaceuticals is a privately held company located in Irving, Texas that aims to translate innovative research into breakthrough medicines for difficult-to-treat diseases that have significant unmet needs. Their business model is built around small cross-functional teams, rapid evaluation of projects for biological activity and clinical viability, quick decision-making, and intense analysis of scientific data to determine the direction of individual programs. They are leaders in developing a novel class of drugs with potent transcriptional activity called antioxidant inflammation modulators (AIMs), which are potent activators of the biological transcription factor Nrf2. Reata is engaged in the discovery of small molecule disease-modifying drugs using multiple proprietary platforms, including the stabilization of the normal three-dimensional structure of target proteins or generally enhancing the folding environment of the cell. Protein folding has become an important emerging area of science. Defects in protein folding underlie a large number of genetic diseases including cystic fibrosis, cancer, Alzheimer's disease, and Parkinson's disease.

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- **Time**
  In addition to eliminating two trials, using Balance also allowed Reata to normalize 1152 excel-based titration rules down to just 88, saving the sponsor a substantial amount of time and effort. The total time it took to configure the RTSM aspects of the study was less than two days, excluding user acceptance testing. "I never believed it would be only two days [to get Balance setup], but now I'm a convert," said Manny Medeiros, senior manager of Bioinformatics at Reata. "I was empowered by Medidata's professional services team to do the build. Setup and validation was straightforward, and operating within the system is easy."
- **Risk**
  Using the integrated Rave/Balance platform also helped to significantly reduce Reata's study risk by eliminating custom programming and automating supplies management. Balance is 100 percent configurable, so there was no programming needed. Its unification with Rave helped Reata eliminate complex and error-prone processes that would come with working in disparate RTSM and EDC systems, as well as avoid the arduous process of integrating applications.

Professional Services Value

Reata's relationship with Medidata has grown and developed into a mutually beneficial partnership over several years since leveraging the Balance RTSM functionality of the Medidata Clinical Cloud.

"Some vendors will say, 'Tell us what you want us to do and we'll build it for you,' said Medeiros. "Medidata Professional Services is not like that. They sit with you and say, 'Well, it would be much more efficient if you built it this way.' They give you really good advice on making a more efficient study inside of Balance and Rave."

The Professional Services team led Reata though the study setup process step-by-step, offering consultative advice based on deep industry knowledge and experience. "The Professional Services group is an absolutely incredible resource," Medeiros added. "They taught me everything I needed to know so I could do it myself—quickly, easily and correctly... the first time."

The Reata team was pleased with the Medidata Professional Services implementation team and how efficiently they were able to execute the knowledge transfer. "What Medidata brings to the table, in addition to deep subject matter expertise, is the willingness to keep working until it is right," stated Gibson "'We can't do that' was never a phrase we heard from their Professional Services team."

About Medidata

Medidata Solutions is the leading global provider of cloud-based solutions for clinical research in life sciences, transforming clinical development through its advanced applications and intelligent data analytics. The Medidata Clinical Cloud™ brings new levels of productivity and quality to the clinical testing of promising medical treatments, from study design and planning through execution, management and reporting. We are committed to advancing the competitive and scientific goals of global customers, which include over 90% of the top 25 global pharmaceutical companies; innovative biotech, diagnostic and device firms; leading academic medical centers; and contract research organizations.

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