

Reata Saves Millions Leveraging the Adaptive Functionality of Medidata Rave RTSM

The Challenge

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 a detailed protocol. Based on accrued in-study data, Reata wanted to accommodate dose adjustments (escalations, reductions) and cohort size changes during the trial. With this level of complexity, finding the right solution was critical to the trial's success.

The study had a level of complexity that prompted Reata to look outside the traditional IRT vendors to handle complexity and evolving study design. Most IRT solutions required expensive and time-consuming programming to support adaptive design — neither acceptable to Reata.

The Solution

Reata identified Medidata Rave RTSM as the most flexible cloud-based solution that supports robust treatment design, including rule-based dosing. RTSM offered agile functionality to support dose titration and the ability to drop a study arm quickly and easily.

Additional benefits that compelled Reata to select Rave RTSM included the following:

- Reata already used Rave EDC on several studies, so adding Rave RTSM reduced training and provided a positive site experience. This was important to the sponsor since the trial's small patient population added additional stress to ensure that enrollment was efficient and error-free to maximize patient satisfaction and minimize the dropout rate.
- Rave RTSM was the only 100% configurable solution available on the market. Because no coding was needed, study setup and in-study modifications were fast and easy—making RTSM the obvious choice.
- Rave RTSM's integration with Rave EDC allowed Reata to use a single interface for patient data entry, randomization, and dispensation. This delivered unmatched agility and control. Two key RTSM benefits were stratification and dosing capabilities for Reata's complex build.

Reata gained efficiencies and flexibility by leveraging RTSM's unique capabilities within the unified Rave platform to execute this innovative trial successfully.

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

“We needed a system that accommodated our needs and could be easily modified during the trial. We found that system in Medidata. Their randomization and trial supply functionality present a unified solution with Rave EDC, so everything works together seamlessly. Rave RTSM is a ‘best-in-class’ solution that did not financially constrain us.”

The Impact

The value Reata gained from Rave RTSM is immense. Medidata's platform empowered Reata to pursue an adaptive trial, merging three studies into one. With RTSM, Reata accelerated an ambitious trial despite complex requirements, achieving process efficiencies and driving value across R&D. The system's flexibility and control provided substantive benefits across trial execution, timelines, and downstream processes, including:

- **Cost Savings:** Reata's adaptive trial design with RTSM enabled real-time dosing assessments, eliminating the need for separate dosing studies. The flexibility of RTSM was key in supporting mid-study modifications as an adaptive protocol. This allowed for considerable time and cost reductions compared to conventional IRT coding approaches. The estimated per-trial savings from adaptivity were in the millions - showcasing RTSM's value.
- **Time Savings:** Rave RTSM allowed Reata to optimize complex dosing rules beyond eliminating study instances. RTSM reduced 1152 Excel-based titration rules to just 88 - saving massive configuration effort. The total time it took to configure the RTSM aspects of the study was less than two days, excluding user acceptance testing. As Reata's Manny Medeiros, senior manager of Bioinformatics, noted: "I never believed it would be only two days [to get Rave RTSM setup], but now I'm a convert! Medidata's professional services team empowered me to do the build. Setup and validation were straightforward, and operating within the system is easy."
- **Risk Reduction:** The integrated Rave EDC/Rave RTSM platform also reduced study risks for Reata by eliminating custom coding and automating supplies management. Without programming needs or complex integrations, Reata lowered implementation barriers and operational risks. The unified Medidata platform also streamlined processes that would otherwise involve error-prone integration across separate EDC and IRT systems.

Professional Services Value

Reata greatly benefited from partnering with Medidata's Professional Services team to implement their clinical trial platform. The seasoned consultants offered invaluable guidance at each stage of the study build process, leveraging their deep industry expertise to provide tailored recommendations aligned to Reata's specific protocol needs.

The hands-on, collaborative approach of the Professional Services team enabled smooth and efficient knowledge transfer to Reata's staff. Their consultative style and meticulous attention to detail ensured the optimal platform configuration to support Reata's complex study requirements. Arthur Gibson, III, AVP of Bioinformatics at Reata Pharmaceuticals, shared: "The Professional Services group is an incredible resource. They taught me everything I needed to know so I could do it quickly, easily, and correctly... the first time... What Medidata brings to the table, in addition to deep subject matter expertise, is the willingness to keep working until it is right."

About Rave RTSM

Medidata Rave RTSM heralds a new generation of cloud-based RTSM capabilities include:

- Unparalleled agility and control for project sponsors and CROs
- New user paradigm-based on an accessible, 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