

Private Immuno-Oncology Company Transitions to Medidata RTSM Solution for Adaptive Phase-III Oncology Study

The Challenge

A private immuno-oncology company was two years into an oncology Phase-III vaccine study when they decided to transition from their current interactive voice response (IVR) system to a randomization and trial supply management (RTSM) system. Managing dozens of sites was cumbersome enough but also managing multiple technology partners had become inefficient. Their current solution was just not flexible enough to meet the needs of their complex trial design and they were concerned about the risk of using so many systems.

This sponsor wanted to centralize their study tools under one vendor who could offer efficient randomization, flexible supply planning and direct real-time access to data without requiring vendor intervention or added cost. They were also concerned that they did not have the expertise or resources in-house to manage such a complex transition. They turned to the contract research organizations (CROs) that were bidding on the transition of the study and asked for recommendations. The majority of the CROs recommended Medidata, knowing that its unified electronic data capture (EDC) and RTSM solution—Medidata Rave® and Medidata Balance®—would offer the efficiencies needed.

The biggest challenge faced by the sponsor, however, was switching systems mid-study. Since the study was in progress, downtime had to be minimized. Adding to the complexity of this transition, subjects had already been randomized in the legacy IVR system for the first part of the study. Data had to be backfilled into Balance so when the cutover occurred in production, blinded dosing would continue without disruption for the remainder of the first part of the study. With new enrollment of the study scheduled to begin in Fall 2014, the project team had to configure Balance to meet the immediate study needs for dosing, as well as the future study needs, upon implementation.

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 interactive voice and web response (IVR/IWR) 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.

The Solution

Medidata Balance was the obvious choice as it addressed all of the challenges their current system could not. It was specifically selected based on the following key needs:

Efficient Randomization

Balance's seamless workflow within Rave allows end-users to randomize and dose subjects upon enrollment without leaving Rave. This meant that Balance could eliminate manual inefficiencies and risk caused by transferring data between a non-interfaced EDC and IVR system. They were also able to reduce the time taken to randomize patients by eliminating several time-consuming steps. As a result, Balance met the sponsor's technology needs, while Medidata's client enablement procedures met their vendor criteria.

On-Demand Data View

Having the ability to view data at their convenience was very important as their old system required a series of six reports to be run and downloaded whenever they needed to view trial data. With Balance being unified with Rave, all of the data could be viewed at any point during the study, eliminating the need for running and downloading or printing reports. In fact, the director of clinical operations was able to quickly view each patient and all of the corresponding visit dates on demand. This was something that was not available from one place in their previous system and was particularly important to review on a regular basis.

In-Process Supply Plan Adjustment

Employing an adaptive methodology presents as many challenges as it does benefits. With the type of adaptive design being used for this study, having the ability to make mid-study supply changes was critical. The old system did not allow supply plans to be individually tailored to sites. With Balance, modifying supply plans was easily done within minutes. Having the ability to quickly modify the supply plan takes supply management off the critical path and ultimately reduces the overall cost of supplies.

Medidata Professional Services

While Balance met their technology needs, the sponsor also needed someone with the experience to:

- Provide the change management expertise around the transition
- Lead the sponsor, their CRO and other vendors through the critical transition points keeping everyone on schedule and within budget — something challenging with this type of project
- Offering implementation consultation every step of the way

Medidata provided technology as well as implementation expertise, and the combination of both ensured the sponsor's project success and satisfaction with Medidata Solutions.

The Impact

The Balance transition was completed in only 12 weeks—three weeks less than the 15 weeks it typically takes to set up a traditional IVR system for a new study. Because Balance is configured and requires no custom coding, the system setup and implementation took minimal time. The majority of the 12 weeks was spent ensuring there was no data lost—a process that involved intensive testing, validation and team collaboration.

The sponsor selected Medidata to lead the team of multiple CROs, vendors and Balance product developers involved in the rescue, including the legacy IVR system vendor. Medidata was the only vendor who demonstrated the level of change management expertise required to coordinate a project of this complexity. In the end, all the data was successfully transitioned without any error and randomization continued seamlessly in the second part of the study. The overall RTSM process was streamlined and made more efficient.

Medidata Professional Services employed their rescue study protocol, which leads the sponsor through the transition, stopping at each decision point to provide consultation. The Medidata Professional Services team ensures the sponsor understands their options and the risks of each decision, as well as empowers sponsors to chart their study course with the assistance of an experienced partner. The director of clinical operations said, "Medidata made the transition amazingly easy and we are very grateful for Balance and the Medidata Professional Services team."

About Medidata

Medidata Solutions is a leading global provider of cloud-based clinical development solutions that enhance the efficiency of customers' clinical trials. Medidata's advanced platform lowers the total cost of clinical development by optimizing clinical trials from concept to conclusion: from study and protocol design, trial planning and budgeting, site negotiation, clinical portal, trial management, randomization and trial supply management, clinical data capture and management, safety events capture, medical coding to business analytics. Our customers include biopharmaceutical, medical device and diagnostic companies, academic and government institutions, CROs and other research organizations, encompassing 20 of the top 25 global pharmaceutical companies as well as research organizations of all sizes.

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