

Randomization Solution Speeds Oncology Study through Integrated Platform and Rapid CRO Training

When a midmarket pharmaceutical company kicked off a Phase II oncology trial with a global contract research organization (CRO), it looked to Medidata to provide an innovative randomization solution with comprehensive training to get the study up and running quickly.

The Challenge

A mid-market pharmaceutical company designed a Phase II study in breast cancer. The trial would involve 200 patients enrolled across 25 sites and required a stratified randomization scheme, invoking a dynamic randomization algorithm. The sponsor outsourced trial management to a global CRO.

The sponsor required both randomization and electronic data capture (EDC) tools. The CRO was a Medidata Services Partner accredited in Medidata Rave®, the sponsor's preferred system for clinical data capture, management and reporting. However, the sponsor did not have a standard randomization system. The sponsor also required that randomization and EDC be integrated, helping drive site productivity by providing one system for randomization and data entry. The use of an integrated solution would minimize data reconciliation and data quality checks, helping to speed overall trial timelines.

The Solution

With Medidata Rave already selected, the sponsor needed a randomization solution that would easily integrate with it. The sponsor evaluated a number of options, including Medidata Balance™, a solution with a unique and unified approach to randomization and trial supply management. Balance offered several advantages over traditional randomization approaches:

- **Powerful Randomization:** Using a Dynamic Allocation algorithm, as selections are made to arms, Balance continually adjusts its next selections to ensure balance is maintained.
- **Simulation Capability for Streamlined Study Setup:** Complete study randomization can be designed from a single interface screen. A built-in simulation tool expedites design testing and ensures preservation of the integrity of the study randomization schema.

The Challenge

For a 200-patient Phase II oncology study to be conducted across 25 US sites, a midmarket pharmaceutical company sought a robust integrated solution for randomization and electronic data capture. It also required a solution that its CRO could quickly configure and implement and that sites would find easy to use.

The Solution

The sponsor and CRO selected Medidata Balance, an innovative randomization and trial supply management (RTSM) system that comes pre-integrated with Medidata Rave, a market-leading electronic data capture (EDC) and clinical data management (CDM) solution. Medidata University's in-depth training options and the Medidata Partner Program, which enables and accredits Medidata Services Partners, were at hand to ensure that the CRO was quickly trained to configure and implement this site-friendly solution with integrated randomization and EDC.

Business Impact

Thanks to the solution's intuitive design—including unique simulation tools— and Medidata training, the CRO was able to be trained quickly on this new technology and quickly configure Medidata Rave and Medidata Balance to have sites up and running quickly. Site work was eased by having one intuitive interface for randomization and patient data capture.

- **Pre-Built Integration for Faster Implementation:** Study timelines can be improved through the pre-built integration of Balance with Rave.
- **Configurable, Pre-Validated Software:** Balance is configured (not custom written) for the specific study and has been validated in advance. This reduces the risk and delay caused by errors that could occur if custom software was required.
- **Comprehensive CRO Enablement:** Medidata University's training packages help teams quickly get up to speed on Balance. Moreover, the Medidata Partner Program offers a Balance accreditation, so that CROs can get rapid in-depth training and sponsors can be assured their Medidata Services Partner is applying system best practices.
- **Ease of Use for Site Satisfaction:** Site instructions are delivered directly in electronic case report forms (eCRFs) in Rave. Site staff enjoy unprecedented simplicity and accuracy of operation with a single browser interface for all subject randomization and EDC requirements.

With their criteria met, the choice was obvious.

The Business Impact

Choosing Medidata Balance generated strong results for the sponsor:

- **Effective CRO On-Boarding:** As a first-time user of Medidata Balance, the CRO underwent a two-day training program to position it to fully leverage Balance's features and advantages. The team could quickly move on to configuration and implementation.
- **Rapid Study Design:** The CRO project biostatistician used the Balance design tool to create and test the design using the built-in simulator that confirmed the randomization schema. Because Balance and Rave were pre-integrated, user acceptance testing of the Balance configuration was conducted within the Rave eCRF testing. Deployment that would have taken two months with other solutions was complete in less than two weeks.
- **Streamlined Site Workflow:** With randomization functionality merged into the flow of Rave screens, site staff can interact with one system for randomization and data collection, easing their workflow.
- **Accelerated Trial Timelines:** Overall, the integrated solution with its common database helps shorten trial timelines by eliminating data reconciliation that would be required of two different systems.

The integrated Medidata Balance-Rave solution is the right choice for sponsors seeking rapid study starts, high site productivity and satisfaction, and streamlined data management for faster time to database lock.

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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