Medidata Rave RTSM Agile Randomization and Trial Supply Management

Rave RTSM heralds a new generation of cloud-based Interactive Response Technology (IRT) capabilities.

- New user paradigm based on a simple, 100% configurable interface
- Unified with Medidata Rave EDC (electronic data capture) system as a build by Medidata, CRO or sponsor
- Superior cloud-based, agile technology to streamline design and provide real-time visibility into operations

Experience True Study Agility

As sponsors strive to realize greater return on investment (ROI), clinical trials increasingly face changing requirements and priorities. Traditional Interactive Voice Response (IVR) and Interactive Web Response (IWR) systems were designed to address static, pre-defined requirements leading to increased development timelines. RTSM handles complex requirements, avoids pre-defined requirements, and enables quick and easy study change implementation, allowing for greater flexibility in today's adaptive environment. Now, prototypes can be established in hours, setup can be completed in weeks and mid-study changes such as removing a treatment arm can be made without a vendor change order thus eliminating unnecessary downtime and inconvenience to end users or patients. Tightly pre-validated and integrated controls accompany this flexibility to ensure all changes are authorized and tracked.

Manage Trial Complexity Simply and Elegantly

Protocol complexity in today's trials is increasing as sponsors strive to get their drug to market faster. The new study paradigm calls for larger studies that have planned checkpoints, more complex randomization schemes, a greater number of treatment arms, and support for cohorts, titration, and changes to dosing. RTSM enables sponsors to manage these complex protocols without sacrificing speed or quality. Today's Study Managers focus on patient recruitment and meeting timelines. RTSM addresses these challenges by shortening system development time, bringing faster and more flexible mid-study changes, and by reducing data reconciliation during study closeout with a unified interface with Rave EDC.

A COMPLETE CLINICAL TRIAL SOLUTION

Rich features extend from design through operation

- Pre-validated randomization options for permuted block or dynamic allocation
- Powerful features that support adaptive trials such as cohort management and ability to make mid-study changes to treatments and visit schedules
- Simulate randomization designs to enhance confidence in randomization scheme chosen
- Robust treatment designs include titration, rule-based dosing, and stratification
- Ability to randomize in real-time from the operating room
- Ability to develop and execute flexible supply plans including buffer and predictive approaches
- Ability to copy designs instantly among studies
- Significant reduction in implementation gets your study started sooner
- Self-generating specification documents and full audit trail
- Single vendor source and support
- Support desk with 24/7 global coverage

medidata

Flexible Implementation Options

Rave RTSM offers multiple methods to get your study live. Medidata can utilize their experienced team of project managers and implementation consultants to do the build for the Sponsor; One of Medidata's certified partners can manage the implementation; The Sponsor can become self-enabled and complete implementation thus taking control of their utilization and driving cost savings for their organization. Regardless of the approach that is utilized, the Unified RTSM/EDC solution will streamline your RTSM operations.

Cloud-Based User Paradigm

Rave RTSM is built on the Rave Clinical Cloud's unified data platform, which enables a single source of truth for all study-related data across your entire portfolio. This ensures that the right treatment is delivered to the right patient at the right time automatically eliminating the need for multiple data entry. This can be accomplished because once data is entered, the platform masters and populates it throughout the end-to-end suite of Rave applications. The power of the platform allows patients to be auto-enrolled, consented and randomized instantly in one single platform if using Rave eConsent, Rave eCOA, Rave RTSM and Rave EDC.

Robust Randomization Design

As a cloud-based solution accessible 24/7, Rave RTSM offers a choice of pre- validated methods for rapid study planning and start-up. Permuted block studies can be set up in minutes and, with integrated block list generation or the uploading of externally-generated lists, the process is smooth and seamless. This reduces costs associated with third-party randomization list builds. For studies using dynamic allocation, RTSM offers a built-in, pre-validated algorithm that can be configured in minutes. The built-in simulator enables study teams to immediately analyze the chosen randomization design, comparing the balance achieved using either the permuted block or dynamic methods. RTSM supports adaptive trials by providing the ability to manage cohorts, add or drop treatment arms mid-study, and adjust dosing factors and visit schedules. All of this can be done in a matter of hours. No more waiting for system changes that take weeks and cost thousands of dollars.

THE PLATFORM OF CHOICE FOR CLINICAL RESEARCH

The Medidata Rave Clinical Cloud is the cutting-edge platform that transforms the clinical trial experience for patients, sponsors, CROs, and research sites. Designed with a unified data platform, the Rave Clinical Cloud creates a single source of truth for all study-related data. Simply put, enter data once and let the platform master and populate it throughout the end-to-end suite of Rave applications. Optimize operational execution, decrease the data entry and maintenance burden, and reduce the number of clinical systems across your study teams. Throw away your list of passwords, you are now on a truly unified platform.

About Medidata

Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,400 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data.

Medidata, a Dassault Systèmes company (Euronext Paris: #13065, DSY. PA), is headquartered in New York City and has offices around the world to meet the needs of its customers. Discover more at **www.medidata.com** and follow us **@medidata**, The Operating System for Life Sciences™.

info@medidata.com | +1 866 515 6044