

Medidata Rave RTSM Agile Randomization and Trial Supply Management

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

- New user paradigm based on a simple, highly-configurable interface
- Unified with electronic data capture (EDC) system Medidata Rave EDC (formerly Medidata Rave®) or 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 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. Medidata Rave RTSM handles complex 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. Tightly 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. Medidata Rave RTSM enables sponsors to manage these complex protocols without sacrificing speed or quality. Today's Study Managers focus on patient recruitment and meeting timelines. Rave 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.

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

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.

New Cloud-Based User Paradigm

As a cloud-based solution that is accessible 24 hours a day, 7 days a week, Rave RTSM offers sponsors, CROs and sites a simple interface facilitating study execution through day-to-day operations. Rave RTSM delivers powerful configuration capabilities in a clean, intelligent interface that enables clinical data managers, biostatisticians and other members of the research team to benefit from easy-to-define rules and design. For example, an authorized designer can easily add an arm or factor, modify variables like ratios and probabilities or run a configuration report on demand. Sites also benefit from the simple-to-use Rave EDC interface, resulting in reduced staff training costs and an enhanced user experience.

Robust Randomization Design

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, Rave 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. Rave RTSM supports adaptive trials by providing the ability to manage cohorts, add or drop treatment arms mid-study, and also 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.

Rave Data Capture and Management

Rave Data Capture and Management powers today's targeted therapies – all of the data, all of the protocol, in one place, going beyond clinic and lab data to also include data from sensors, apps, images, genomics and RWE (Real World Evidence)

By capturing and integrating such a wide array of study data, **Rave Data Capture and Management** also automates many of the most challenging data management workflows across randomization, supply, coding, and safety. It is now possible for a patient to be electronically consented, randomized, provided their first supply, and automatically be coded – all in their first visit.

About Us

**Medidata is leading the digital transformation of life sciences with the world's most-used platform for clinical development, commercial and real-world data. Powered by artificial intelligence and delivered by #1 ranked industry experts, the Intelligent Platform for Life Sciences helps pharmaceutical, biotech, medical device companies and academic researchers accelerate value, minimize risk and optimize outcomes. Medidata serves more than 1,000 customers and partners worldwide and empowers more than 100,000 certified users every day to create hope for millions of patients. Discover the future of life sciences: [medidata.com](https://www.medidata.com)
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