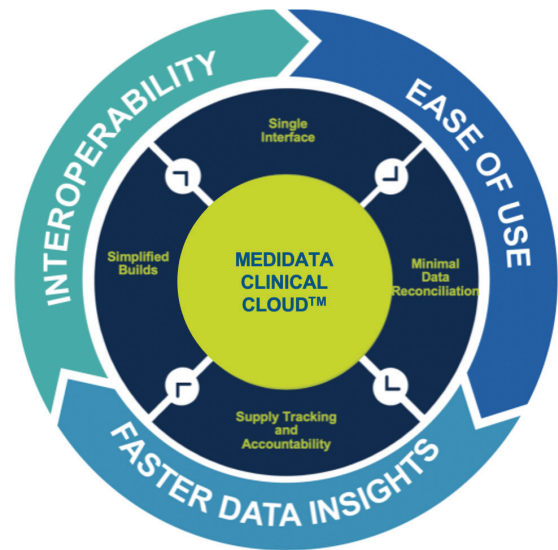


Rave RTSM: Agile Randomization and Trial Supply Management

Rave RTSM is a configurable randomization and trial supply management solution unified with Rave EDC that provides an agile, real-time approach to study randomization, dosing design and site/depot supply management for clinical and medical device trials. Based on a simple, 100% configurable interface and unified with Rave EDC (electronic data capture), Rave RTSM is a superior agile technology designed to streamline and provide real-time visibility into your operations.

UNLOCK THE POWER OF RANDOMIZATION AND TRIAL SUPPLY MANAGEMENT ON THE MEDIDATA RAVE CLINICAL CLOUD

- Simplified implementation and execution
- Extensive and flexible supply management
- Elimination of reconciliation
- Reduction of risk
- Robust data ingestion to one data repository



Product Benefits

Rave RTSM, as part of the Medidata Clinical Cloud™, drives greater value and flexibility.

Abbreviate Timelines

- 2-3 week study build
- UAT execution in < 1 day
- 25% faster eCRF data entry

Reduced Risk

- 100% configurable
- Pre-validation reduces risk
- Roles are predefined eliminates unblinding

Ease of Integration

- Unified Electronic Supply Accountability
- Automated depot data flow
- Forecasting with multiple vendors

Easy Set Up

- Real time adjustments with no downtime
- Roll out protocol changes in hours rather than days
- Direct-to-Patient capabilities

Rave RTSM Features

Robust Cohort Management

Powerful features that support adaptive trials and ability to make mid-study changes to treatments and visit schedules with limited to no downtime. Be able to move patients between cohorts.

Direct-to-Patient

Only Medidata's Rave RTSM has the flexibility to define at a site/visit/patient level when to trigger a DtP shipment or source from site stock with no down time.

Supply Management

Comprehensive Supply Management schemes (buffer & predictive) w/ability to alter plans in real-time throughout the study. Utilize pooling to save on inventory.

Supply Integration Service

Rave RTSM is able to utilize a re-validated 2-way integration with large depot vendors for shipment to sites or Direct-to-Patient shipments.

Supply Accountability

Rave EDC + Rave RTSM unified process is pre-validated, highly flexible and can be significantly streamlined ensuring efficiency, timeliness and accurate data by eliminating the need for separate logs on multiple systems.

Visit Cycles

Rave RTSM supports studies with repeating visit cycles, including oncology trials by reducing study complexity, set up time, and human error.

Edit Live Design

Edit Live Design allows post-go live changes in RTSM as a result of protocol amendments.

Reporting

Robust supply management reporting for blinded and unblinded users. Flexibility to run ad hoc or scheduled reports for any frequency and destination.

Drug Pooling

Rave RTSM's drug pooling feature addresses the need to make efficient use of trial supply across multiple studies.

Significant Reduction in Key Performance Indicator Cycle Times



The Medidata Advantage

Medidata's innovative approach to randomization and trial supply management enables studies to start sooner and minimizes the potential impact of protocol design changes throughout the study life cycle. Rave RTSM enables execution of adaptive trials focused on personalized medicine and provides robust device tracking and accountability to reduce risk and meet regulatory requirements. Other advantages are:

- Elimination of data reconciliation cost between EDC and IVRS/ RTSM
- Edit Live Design™ simplifies mid-study changes (50-75% reduction in time to make mid-study change)
- A pre-validated, fully configurable system that simplifies build and gets teams to User Acceptance Testing (UAT) easier and faster (> 50% reduction in UAT cycle time)
- More efficient Med Device trial execution and device accountability

Medidata, a Dassault Systèmes company, is leading the digital transformation of life sciences.

Discover more at www.medidata.com and follow us @medidata. Contact us at info@medidata.com | +1 866 515 6044