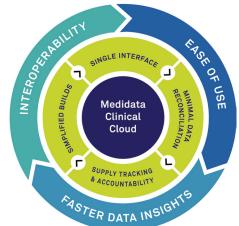


Rave RTSM Agile Randomization and Trial Supply Management

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 Randominzation and Trial Supply Management on The Medidata Clinical Cloud®

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



Rave RTSM 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

Ease of Integration

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

Reduced Risk

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

Easy Set Up

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



Features of Rave RTSM

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.

Supply Integration Service

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

Edit Live Design

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

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 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.

Reporting

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

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.

Visit Cycles

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

Drug Pooling

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

Organizations using Rave RTSM Reach their Study Milestones Faster

18%

Reduction in EDC build duration with Rave RTSM¹

35%
Achieve EDC
database lock*
sooner with Rave RTSM²

25%

Reduction in data entry time using Rave EDC+RTSM³

- 1 Difference in median build time for Rave EDC + Rave RTSM vs. Rave EDC only studies. Study build defined as study creation to eCRF finalization n=818 per group (*p<0.05); Reduction of 23 Days.
- 2 Difference in median LPLV to DBL time for Rave EDC + Rave RTSM vs. Rave EDC only studies n=144 per group (p<0.05) 2017 to 2021; Reduction of 17 Days.
- 3 Difference in data entry time using Rave EDC+RTSM using a customer validated.

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 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