

# Rave RTSM: Even the Most Complex Studies Reach Milestones Faster

Through a simple, 100% configurable interface and unification with Rave EDC within the Medidata Platform, RTSM has robust functionality to support both simple and complex study designs. RTSM reduces timelines and eases mid-study changes while ensuring a single source of truth for your clinical and medical device trials. From complex randomization and adaptive trials to Direct-to-Patient and repeating visit cycles, when you choose Rave RTSM you have immediate access to all current and future features available for your study.

## Unlock The Power of Randomization and Trial Supply Management on The Medidata Platform

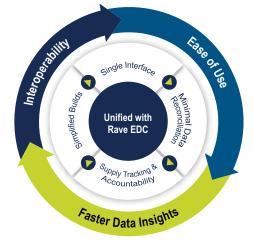
Unified with Rave EDC

Simplified implementation and execution

Extensive and flexible supply management

Reduction of reconciliation and risk

Single data source for real-time data visibility and insights



## Features of Rave RTSM

#### **Robust Cohort Management**

Powerful cohort features that enable the execution of complex adaptive trials, ranging from study teams controlling study progression by opening and closing cohorts in real-time to the addition of new cohorts to the implementation of mid-study changes with limited to no downtime.

#### **Edit Live Design (ELD)**

ELD allows post-go live changes in RTSM with little to no downtime, simplifying the protocol amendment process.

#### **Direct-to-Patient (DtP)**

Only Rave RTSM allows patients to confirm receipt of supplies in DtP studies using the myMedidata App and has the flexibility to define at a site, visit, or patient level when to trigger a DtP shipment versus dispense from site inventory, fully supporting decentralized trials (DCT).

#### **Visit Cycles**

Rave RTSM uniquely supports studies with repeating visit series over fixed or indefinite time periods reducing study complexity, set-up time, and human error.

#### Multi-Dose Vial

Rave RTSM supports the use of multi-dose vials in clinical trials, allowing the dispensation of a single item to multiple patients and capturing viability information of the remaining doses.

#### **Supply Integration Service**

Rave RTSM utilizes a standard pre-validated 2-way integration with large depot vendors for supply shipments to sites or Direct-to-Patient shipments.

#### **Electronic Supply Accountability (eSA)**

Rave EDC + Rave RTSM provide the only fully unified eSA experience, significantly increasing efficiency and reducing timelines by eliminating the need for paper logs or multiple systems and consolidating all IP data for study closeout and accurate data reporting.

#### **Supply Management**

The comprehensive buffer and predictive supply management schemes are easily modified in real-time, supporting changing inventory management needs throughout the life of the study.

#### **Forecasting**

Forecasting capabilities project inventory needs over time for existing patients and simulate future patient needs to prevent stockouts and optimize supply and labeling.

#### **Drug Pooling**

Drug pooling at both sites and depots allows for the efficient use of trial supply materials across multiple studies.



## Benefits Across Study Stakeholders

Rave RTSM is designed to work seamlessly with Rave EDC. Medidata's model offers a single source of truth with the following benefits:



#### **Patients**



Sites



**CRAs** 



Clinical Operations /PMs



Data Managers



Supply Managers

Flexible delivery options available with Direct-to-Patient

Simplified communication on receipt of IP

One system

Single data entry

Single logon

Single data entry

Limited data reconciliation

Allows CRAs to focus on higher-value activities

Centralized data for real-time oversight of study progression

Accelerated database lock due to limited data reconciliation

One system

Cleaner data

No integration with external systems

Full control of supply management planning and tracking

Real-time visibility for preventing stockouts and optimizing supply

Ease of Use/Single Sign On

Faster Startup/Close Out

**Faster Data Access** 

## Rave EDC and RTSM Unified Approach



"Medidata's RTSM solution gives PROMETRIKA a competitive advantage in support of our sponsors' highly complex clinical trials. The [unification] of IRT and EDC shortens trial implementation and validation timelines."

Miganush Stepanians, PhD, President and CEO, PROMETRIKA

Medidata Rave RTSM

**Most Preferred IRT Provid** 

4Source: Industry Standard Research, IRT Report, 2022.

The Medidata RTSM Professional Services Team has the experience, knowledge, and passion to ensure that your RTSM trial experience is positive and successful. From our deep understanding of different randomization algorithms, to complex dosing, titration schemes, and supply strategies, Medidata Professional Services works tirelessly to deliver the utmost value to your sites, patients, and trial outcomes.

## **Organizations** using Rave RTSM reach their study milestones faster

18%

Reduction in EDC build duration with Rave RTSM1

35%

Faster to EDC database lock\* with Rave RTSM<sup>2</sup>

Rave RTSM: Proven Results

25%

Reduction in data entry time using Rave EDC+RTSM3

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=831 per group (\*p<0.05); Reduction of 20 Days.

2Difference in median LPLV to DBL time for Rave EDC + Rave RTSM vs. Rave EDC only studies n=144 per

<sup>3</sup>Difference in data entry time using Rave EDC+RTSM using a customer validated.