

Rave RTSM Introduces Enhancements to Edit Live Design Capabilities

Rave RTSM heralds a new generation of cloud-based Interactive Response Technology (IRT) capabilities that offers flexibility in configuration and mid-study changes with no impact to system downtime to sites or end users. When you edit and change a live study through Edit Live Design, Rave RTSM creates a new, separate study design whereby sites can be assigned to this newer version based on IRB approval status. Edit Live Design provides full version control and access to different testing environments enabling users to validate their updates before they are applied in production. Knowing you have full version control and flexibility of your study design is valuable with the increasing complexity of protocol design and amendments.

EXPERIENCE TRUE STUDY AGILITY

As sponsors strive to realize greater ROI, clinical trials are increasingly faced with changing requirements and priorities. Traditional IRT systems were designed to address static, pre-defined requirements. RTSM handles not only pre-defined requirements but also enables changing requirements to be implemented quickly and easily, resulting in greater flexibility in today's adaptive environment. Now, prototypes can be established in hours, setup can be completed in days and system updates can be completed without the need for a vendor change order. Tightly integrated controls accompany this flexibility to ensure all changes are authorized, tracked, and can be rolled out on a site by site basis to meet IRB approval.

EDIT LIVE DESIGN ENHANCEMENTS

Edit Live Design allows post-go live changes in RTSM as a result of protocol amendments. Existing Edit Live Design features allow users to do the following:

- Add/delete randomization factors and factor states
- Check/uncheck block by site
- Modify dynamic allocation options
- Modify randomization factor weights
- Modify randomization supply check changes
- Add/modify/inactivate treatment compositions
- Modify 'Do Not Dispense' days
- Add visits
- Modify visit windows

New feature enhancements for Edit Live Design include the following:

- Modify dosing factors and treatment arms
- Add/remove numbered items while creating destruction event at site

A Complete Clinical Trial Solution

Rich features extend from design through operation

- Pre-validated randomization options for permuted block or dynamic allocation
- Simulation of randomization designs for maximum design confidence
- Ability to randomize in real-time from the operating room
- Ability to copy designs instantly among studies
- Fast implementation to better meet the critical path timelines
- Self-generating specification documents and full audit trail
- Single vendor source and support
- Dedicated RTSM support desk with 24/7 global coverage
- Increase savings by eliminating change orders

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.

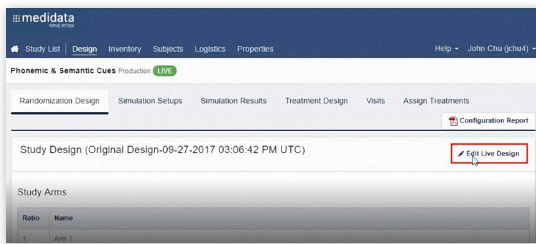
RTSM SOLUTION

Rave RTSM is built on the Medidata Rave Clinical Cloud's unified 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.

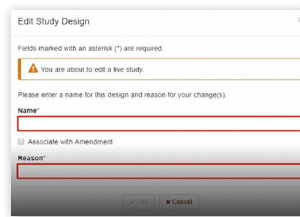
The flexibility of RTSM provides for real-time parameter settings to randomization method, supply management, inventory and logistics, shipments, and enrollment caps which brings value to sponsors to manage mid-study changes as needed in the ever changing world and complexity of protocol trial design. (See Exhibit 1 below):

Exhibit 1:

Step 1: Select study in RTSM and click 'Edit Live Design'



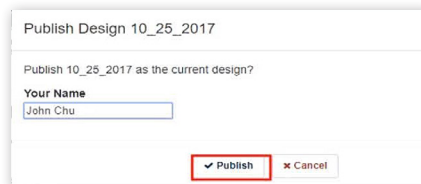
Step 2: In the Pop-Up Window, enter name and reason for making the change.



Step 3: You can also associate it with a study protocol amendment as needed by selecting the field 'Associate with Amendment.'



Step 4: Once you click 'Edit', the new study design is created in draft mode within RTSM. Begin making updates in RTSM as needed. Updates may be applied to specific versions and/or sites. Note: For Dynamic Allocation studies, all sites get promoted to the new design when published.



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.

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