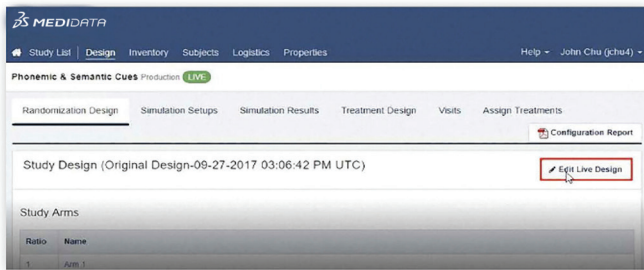


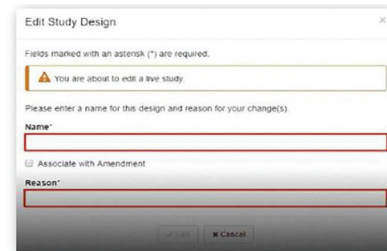
# Rave RTSM and Edit Live Design™

Rave RTSM Edit Live Design capabilities give you the flexibility to make 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. Study Team roles can associate sites to different design versions based on country-specific approvals. 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 invaluable with the increasing complexity of protocol design and amendments.

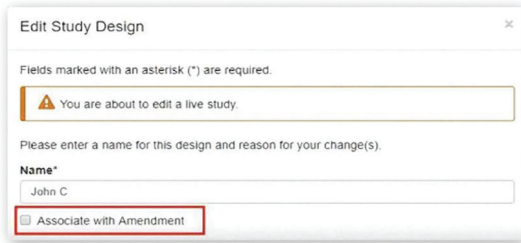
Step 1: Select study in RTSM and click 'Edit Live Design'



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.



## Rave RTSM Edit Live Design Benefits

Edit Live Design enables mid-study changes completed in minutes with the ability to test all changes in any auxiliary environment.

### Manage Multiple Active Designs

- Maintain multiple active designs in parallel
- Associate a design version to protocol amendment name
- Allocate single or multiple patient randomization list(s)

### Modify Stratification Easily

- Add or remove stratification factor(s)
- Update study from no stratification to one or more factors
- Cap stratification changes when needed

### Associate Sites to Designs

- Associate individual sites or an entire country to a design version
- Change design version for a site in seconds
- Create multiple design versions as needed

### Minimize or Eliminate Downtime

- Modify active studies in minutes with pre-validated features
- Easily manage randomization assignment, dispensation and/or study visits
- Continue to enroll patients while drafting a new design version

## Rave RTSM Edit Live Design Features:

**Add/delete randomization factors and factor states**

**Add/modify/inactivate treatment scenarios**

**Modify dynamic allocation options**

**Modify 'Do Not Dispense' days**

**Modify randomization factor weights**

**Add/modify visits**

**Modify randomization supply check changes**

## The Medidata Advantage

The flexibility of Rave RTSM Edit Live Design functionality provides the ability to make mid-study changes in real-time to randomization factors, dispensation rules and study visits without costly change orders and no down time for systems, sites or users. Edit Live Design is truly a state-of-the-art capability facilitating your ability to manage protocol amendments in a simple, quick and completely pre-validated manner.