















9 OpenClinica Randomize

OpenClinica Randomize was introduced in OpenClinica version 3.9. This optional, add-on module is available to our Enterprise customers upon request on a study-by-study basis. Once you request access, your OpenClinica sales and support teams will work with you to get your study set up for randomization.

To Request OpenClinica Randomize:

On the Build Study page (Tasks > Study Setup > Build Study), in the Randomize line of the Modules section, click  .

| | Task | Status | Count | Mark Complete | Actions |
|---|------------------------------|-------------|------------|--------------------------|---|
| 1 | Create Study | In Progress | NA | <input type="checkbox"/> |   |
| 2 | Create CRF | Not Started | 0 | <input type="checkbox"/> |  |
| 3 | Create Event Definitions | Not Started | 0 | <input type="checkbox"/> |  |
| 4 | Create Subject Group Classes | Not Started | 0 | <input type="checkbox"/> |  |
| 5 | Create Rules | Not Started | 0 | <input type="checkbox"/> |   |
| 6 | Create Sites | Not Started | 0 | <input type="checkbox"/> |  |
| 7 | Assign Users | In Progress | Total : 19 | <input type="checkbox"/> |   |

| | Modules | Status | URL | Actions |
|---|-------------|----------|-----|---|
| | Participate | Disabled | |  |
|  | Randomize | Disabled | |  |

An on-screen message and email notification confirms your request and the Randomize status changes to Pending.

Configuring OpenClinica Randomize

Once Randomize has been enabled for your study, the OpenClinica team will take steps to ensure it is implemented appropriately per your study requirements. You will be able to choose from a variety of randomization protocols such as blocks, random permuted blocks, and minimization. OpenClinica Randomize also supports blinded and unblinded studies, allowing you to display either a treatment group name or treatment group code. You are able to use any CRF variables, and a variety of global variables as stratification factors (such as site) in your randomization.

Randomizing a Patient

The following is provided as an example of one implementation of Randomize based on a study with stratification variables of Age, Gender, and BMI. The steps below outline how to randomize on a patient-by-patient basis. Alternatively, you could randomize all non-randomized patients by running the Randomize rule in batch on the [Manage Rules](#) page.

1. In data entry, schedule and open the Randomization CRF:

Stratif...(3/3) Confirm...(0/1) Randomi...(0/1) -- Select to Jump --

Title: Stratification Factors

Page: Save Exit

Age: Less Than 18

Gender: Male

BMI: 28-35

Return to top Save Exit

2. Depending on your configuration either enter or review the inserted values for the stratification variables and click **Save**.

The Randomize Confirmation section displays:

Stratif...(3/3) Confirm...(0/1) Randomi...(0/1) -- Select to Jump --

Title: Confirmation

Page: Save Exit

Stratification Factors:

Age: Less+Than+18

Gender: Male

BMI: 28-35

Randomization will be performed based on these values. Please confirm these values before responding below.

Ready to randomize? (select one)

Yes

No

Return to top Save Exit

3. Review and confirm the stratification values. To randomize the patient, select **Yes** and click **Save**.

The Randomization section displays with the randomization code in a read-only field:

Stratif...(3/3) Confirm...(0/1) Randomi...(0/1) -- Select to Jump --

Title: Randomization Code

Page: Mark CRF Complete Save Exit

Stratification Factors:

Age: Less+Than+18

Gender: Male

BMI: 28-35

Randomized Group Assignment: JA946 If you see a value here, randomization is complete!


Return to top Mark CRF Complete Save Exit
















4. Mark the CRF complete and click **Save**.




Disabling OpenClinica Randomize

Once all patients for a study have been randomized, you can request that Randomize is disabled. This maintains all of your randomization information for the study, but you will not be able to randomize any new patients.

To disable OpenClinica Randomize:

On the Build Study page (Tasks > Study Setup > Build Study), in the Randomize line of the Modules section, click .

| | Task | Status | Count | Mark Complete | Actions |
|---|------------------------------|-------------|------------|--------------------------|---|
| 1 | Create Study | In Progress | NA | <input type="checkbox"/> |   |
| 2 | Create CRF | In Progress | 25 | <input type="checkbox"/> |   |
| 3 | Create Event Definitions | In Progress | 5 | <input type="checkbox"/> |   |
| 4 | Create Subject Group Classes | In Progress | 2 | <input type="checkbox"/> |   |
| 5 | Create Rules | In Progress | 167 | <input type="checkbox"/> |    |
| 6 | Create Sites | In Progress | 2 | <input type="checkbox"/> |   |
| 7 | Assign Users | In Progress | Total : 23 | <input type="checkbox"/> |   |

| | Modules | Status | URL | Actions |
|--|-------------|----------|---|---|
| | Participate | Disabled | |  |
|  | Randomize | Active | http://openclinica.info:8081 |  |

The Randomize status changes to Disabled.

OpenClinica 3.9 Randomize Notes

Please note the following apply to the 3.9 release of OpenClinica Randomize:

- Patients can only be randomized once. If an error is made when entering any of the stratification values and a patient is randomized based on the incorrect value, that patient cannot be re-randomized even if the stratification value is later corrected. Your Randomize eCRF will be designed to include a confirmation screen that displays the stratification values prior to prompting you to confirm randomization.
- Though the Manage Rules page (Tasks > Monitor and Manage Data > Rules) displays Randomize rules and allows you to view and download those rules, those rules should not be edited. If you need any changes to anything in the randomization process, please contact your OpenClinica support team. Any changes you make to the rules may compromise your randomization.

Approved for publication by Laura Keita. Signed on 2019-02-02 1:01PM

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