

15 OpenClinica Randomize

OpenClinica Randomize allows you to randomize data to ensure that it is unbiased.

Randomize Allows You to:

- Randomize directly within OpenClinica
 - Simple
 - Blocks
 - Random permuted blocks
 - Minimization
 - Multiple
- Stratify by age, sex, site, or any Form item
- Generate randomization lists
- Send email notifications
- Allocate randomization code at follow-up visits
- Manage code lists
- Generate randomization codes for labeling treatment kits

During the configuration process, you can specify one or multiple stratification factor(s) you want to randomize your data by. You can have multiple randomizations in a single study environment. Participants are randomized (in the order they become ready for randomization) only after data has been entered into Forms for each stratification factor has been entered. **Note:** *If you use randomization, you must display the result of the randomization on a Form.*

For example, in one study, the Eligibility Form and the Demographics Form must be filled out prior to randomization. Next, there is a randomize Form that requires a response to a question, **What age will the Participant be at the start of the study**. Underneath, there is a checkbox that says **Randomize**.

The next form displays the randomization assignment. This might be the arm of the study or the kit number.

Once configured, randomization integrates with your Forms. Randomization automatically occurs when data has been added to all fields that are required for stratification. This means that all associated Forms must be marked **Complete**.

For example, if you want to stratify by age, you need a Form with an **Age** field. You must enter data into that field and mark the Form **Complete**. When you have enough Participants with applicable data, the process ensures that all groups (blocks) have a mixed range of ages.

Once randomization has occurred, the randomized value is inserted into the Form specified during configuration. You can then view the randomized value within the Form.

Contact support@openclinica.com to schedule a meeting to discuss your randomization needs.

Approved for publication by Kerry Tamm. Signed on 2020-11-17 2:01PM

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