10 OpenClinica Randomize

This page is for Data Managers and Study Administrators responsible for configuring participant randomization in OpenClinica. It explains how you can use OpenClinica Randomize to assign participants to study groups in an unbiased and controlled manner.

OpenClinica Randomize allows you to set up and manage randomization so participant assignment remains objective and consistent throughout the study.

What you can do with OpenClinica Randomize

You can use OpenClinica Randomize to:

- Perform randomization directly within OpenClinica
- Configure simple or complex randomization methods, including:
  - Block randomization
  - Random permuted blocks
  - Minimization
  - Multiple randomization schemes
- Stratify randomization by age, sex, site, or any Form item
- Generate and manage randomization lists and code lists
- Allocate randomization codes at follow-up visits
- Generate randomization codes for labeling treatment kits
- Send email notifications related to randomization events

How randomization is applied

During configuration, you specify one or more stratification factors that determine how Participants are randomized. You can configure multiple randomizations within a single study environment.

Participants are randomized in the order they become ready for randomization. This occurs only after data for each stratification factor has been entered into the associated Forms.

 Note: If you use randomization, you must display the randomization result on a Form.

Example scenario

1. Ensure the **Eligibility Form** and **Demographics Form** are completed before randomization.
2. Configure a Randomize Form that includes a question such as:
   “What age will the Participant be at the start of the study?”
3. Include a checkbox labeled **Randomize** on this Form.
4. The next Form displays the randomization assignment, such as:
   - Study arm
   - Treatment kit number

Once configured, randomization integrates with your Forms and occurs automatically when:

- All required stratification fields contain data
- All associated Forms are marked **Complete**

For example, if you stratify by age:

- You must include an **Age** field on a Form.
- You must enter data in the **Age** field.
- You must mark the Form **Complete**.

When enough Participants have applicable data, the system ensures that all groups (blocks) contain a balanced range of ages.

After randomization occurs, the assigned value is automatically inserted into the Form specified during configuration. You can view the randomized value directly within the Form.

Support

 Note: OpenClinica Randomize is not a self-service module. You must coordinate with OpenClinica Support to configure and enable this feature for your study.

For assistance with configuring randomization or to discuss your study-specific requirements, contact OpenClinica Support at **support@openclinica.com** to schedule a consultation.

Approved for publication by Kate Lambert. Signed on 2025-12-11 3:49PM

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