

# Randomization

## CCTS Biostatistics Core

May 2024

### Purpose

The REDCap Randomization module can be used:

- For randomized controlled trials (RCTs) that need to assign study participants to different treatment groups.
  - “An RCT is a prospective study following patients forward in time. After agreeing to participate, patients are randomly allocated to one or more interventions or a control group and are followed until a finite date or the occurrence of one or more outcomes of interest.” - Houle S. 2015
- To randomize the survey instruments or data entry forms.

### Steps

#### Outside of REDCap

##### Plan your randomization method

- a. Decide between simple randomization and stratified randomization.
- b. Determine the randomization ratio (e.g., 1:1 for equal allocation to treatment and control groups).
- c. Determine the number of records to be randomized.

##### Generate randomization allocation table

- a. Create the allocation table outside of REDCap using statistical software in collaboration with your team's data scientist.
- b. Ensure the allocation table includes more assignments than the planned sample size to accommodate any unexpected changes or errors.

#### Within REDCap

##### Set up user rights

- a. Define user access rights in the REDCap project. Users with access to Project Design and Setup can set up the Randomization module. [See the User Rights page form more information.](#)
- b. Users accessing the instrument with the randomization field can randomize and view the result. Those requiring blinding should not have access to the instrument.

## Create fields for randomization in Online Designer

- Include fields necessary for randomization in your project using the Online Designer.
- Define inclusion/exclusion criteria used as strata or conditions for randomization using branching logic.
- Create the randomization result field as a radio button (e.g., 0, Control / 1, Treatment). It is best to create this field in a regular data entry form entered by study staff, not in a screening form or survey instrument.

**Set up and test Randomization module in Project Setup** Perform this setup in development status, as no changes are possible in production status. [See this page for more about development and production status.](#)

1. Enable the Randomization module in Project Setup.

2. Click Set up randomization and Complete STEP 1: Define your randomization model.

**STEP 1: Define your randomization model**

This step will allow you to define the randomization model you will be implementing and all its parameters, which includes defining strata (if applicable) and optionally randomizing subjects per group/site (if a multi-site study).

**A) Use stratified randomization?**

It is often necessary to ensure equal treatment among a number of factors. Stratified randomization is the solution to achieve balance within one or more subgroups, such as gender, race, diabetics/non-diabetics, etc. By choosing strata (multiple choice criteria fields), you may then be able to ensure balance within those subgroups. [See me more](#)

**B) Randomize by group/site?**

If this is a multi-center/multi-site project (or something similar), you may want to stratify the randomization by each group/site. You can select an existing multiple choice field that represents the groups/sites, OR you can use Data Access Groups to stratify by group/site.

**C) Choose your randomization field**

This is the field where the allocated randomization (treatment) group will be saved and stored, and is where the Randomize button will appear on your data collection form.

- select a field -

Save randomization model Erase randomization model

- Upload your allocation table following the REDCap format. It should contain column headers matching the field names defined in the Online Designer for the randomization and stratification fields, as well as strata and randomization values. The following example randomizes 12 subjects using stratification by gender.

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1	random	gender													
2		1	1												
3		0	1												
4		0	1												
5		1	1												
6		1	1												
7		1	1												
8		0	2												
9		1	2												
10		0	2												
11		1	2												
12		1	2												
13		0	2												
14															
15															
16															
17															
18															

**Example**

NOTES:

- Do NOT modify the first row, although you may modify, add, or delete any other row in this file.
- Remember that this file is ONLY a template and should NOT be used as-is as your allocation table.
- You do not have to delete this "notes" column when uploading your allocation table (it will be ignored).
- Below is a list of all raw coded values and their corresponding option labels for each strata field and/or Data Access Groups.

Values/labels for "random" (RANDOMIZE):

- 0 control
- 1 treatment

Strata "gender"

- 1 Female
- 2 Male

**STEP 3: Upload your allocation table (CSV file)**

Once you have created your custom allocation table as a CSV file and made sure that you left the format prescribed in the template files from Step 2 above, you may now upload the file below. It will be checked for any possible errors first before it is accepted and stored in REDCap. Please note that you will need to create two different allocation tables: one to be used for testing while your project is in development status and the other for use when in production status. Below are some important reminders before you begin uploading your allocation tables.

**Reminders:**

- Once your project is in production status, the allocation tables will become locked and unmodifiable.
- Be sure to include more assignments in your allocation table than you think you will need (to accommodate possible drop-out and drop-in of subjects).
- Record names (e.g., study ID) should NOT be included as a column in your allocation table, but only the fields listed in the example files from Step 2 above.

Upload allocation table (CSV file) for use in **DEVELOPMENT** status

Choose File No file chosen

Upload File

Not uploaded yet

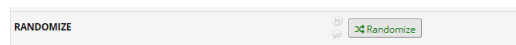
Upload allocation table (CSV file) for use in **PRODUCTION** status

Choose File No file chosen

Upload File

Not uploaded yet

- Test randomization to ensure proper functionality and verify that branching logic works correctly on the data entry form.



### Upload allocation table in production status

- After successful testing in development, upload the final allocation table again for use in production status.
- Any test records and the development allocation table should be deleted when you move the project to production.

**Move your project to production status**

Move the project to production status so that real data may be collected. Once in production, you will not be able to edit the project fields in real time anymore. However, you can make edits in Draft Mode, which will be auto-approved or else might need to be approved by a REDCap administrator before taking effect.

Go to [Move project to production](#)

**Move Project To Production Status?**

Are you sure you wish to leave the DEVELOPMENT stage? If you proceed, the project will be moved to PRODUCTION status so that real data may be collected. If you select the 'Delete ALL data' option below, all current collected data, calendar events, and uploaded documents will be deleted, otherwise all will remain untouched as the project is moved to production.

★ Have you checked the [Check For Identifiers](#) page to ensure all identifier fields have been tagged?

**Keep existing data or delete?**

Keep ALL data saved so far. (30 records)

Delete ALL data in the project (including any survey responses), calendar events, documents uploaded onto forms/surveys, and all archived data export files stored in the File Repository, and any logged events that pertain to data collection.  
Please note, this will delete all MyCap data (including MyCap Participants, Messages, Sync Issues).

Once in production, you will not be able to edit the project fields in real time anymore. However, you can make edits in Draft Mode, which will be auto-approved or else might need to be approved by a REDCap administrator before taking effect.

## After Randomization

**Using randomization value** Randomization results can be used for branching logic, form-skipping logic, Alerts & Notifications, and Automated Survey Invitations.

**Modifying or updating the allocation table are restricted** Once the “Randomize” button is clicked in production, the randomized result and related values used for stratification will be locked and cannot be modified.

In production status, the uploaded allocation table cannot be modified. However, additional values can be added by the REDCap administrator. To request help, [submit a support request](#).

**Handling mistakenly randomized records** After randomization, if a record was mistakenly randomized, there should be a process in place to address this issue. This might involve documenting the error and taking corrective action if necessary (e.g., deleting the whole record and re-entering data to randomize again).