Navigation Sheet – REDCap Randomization Module

Compliance & Data Office

Research Support Office

Karolinska Institutet

Introduction

This guide gives an overview of REDCap's randomization module. By defining your parameters for randomization, REDCap creates a template allocation table which can then be adapted for your project and imported back into REDCap.

Please note that **REDCap does not generate complete randomization tables for you**, the final allocation table has to be created outside of REDCap and later imported. We recommend consulting with a statistician or data analyst when setting up the randomization module in REDCap.

Setting up randomization within REDCap requires access to specific user rights. For more detailed information about REDCap's *User Rights* menu please refer to our navigation sheet about "User Rights & DAGs" on the staff portal.

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Randomization User Rights

As can be seen in the *User Rights* section, there are three levels of access to randomization within REDCap:

- Setup (set up the randomization)
- Dashboard (view allocation dashboard)
- Randomize (perform randomization of participants)

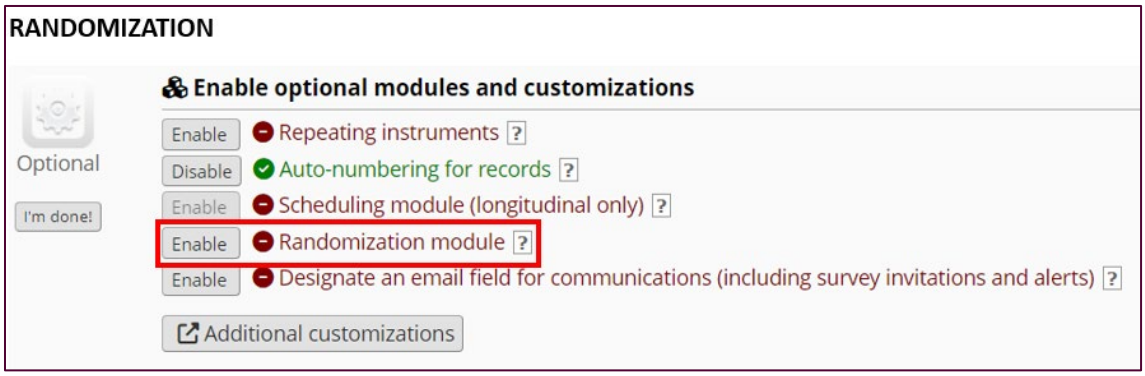
Setup: The user has access to the Setup tab in the *Randomization* menu on the left-hand side. This allows the user to define the randomization by setting up relevant parameters and to upload allocation tables. It is recommended to involve a statistician/data analyst in this process.

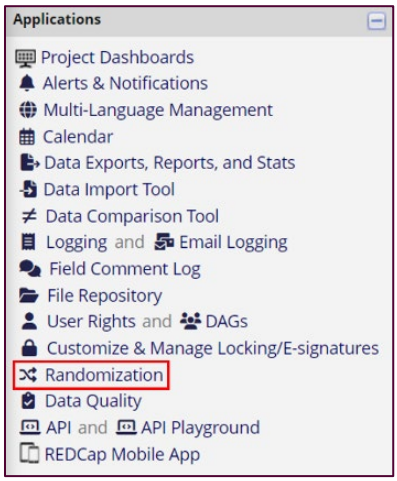
Dashboard: The user has access to the allocation *Dashboard* tab in the *Randomization* menu. This tab shows the allocations for participants / records who have been randomized within REDCap.

Randomize: Users with this access will see the "randomize" button in the chosen instrument and are able to perform randomizations within REDCap.

Activating the Randomization Module

The randomization module can be activated on the *Project Setup* page in your project. Click on "Enable" to activate the module.

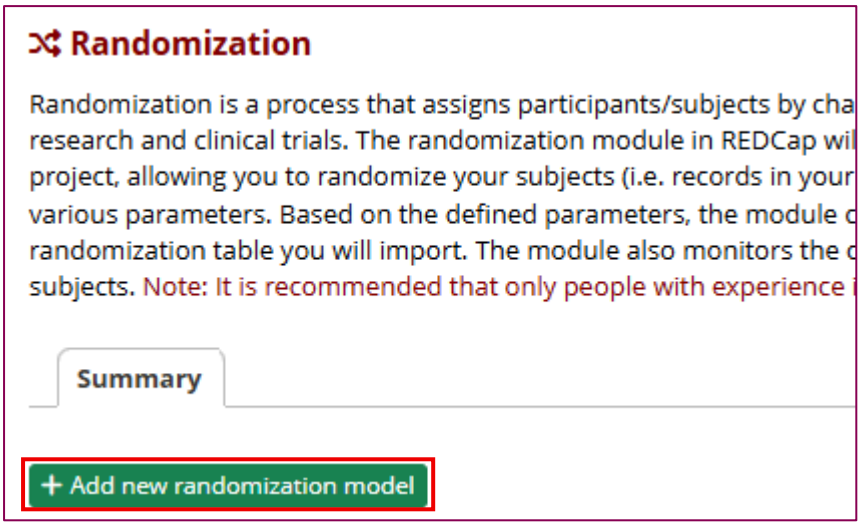




Any user who has been given access to randomization features in their user rights will now be able to see the *Randomization* menu on the left-hand side of the screen.

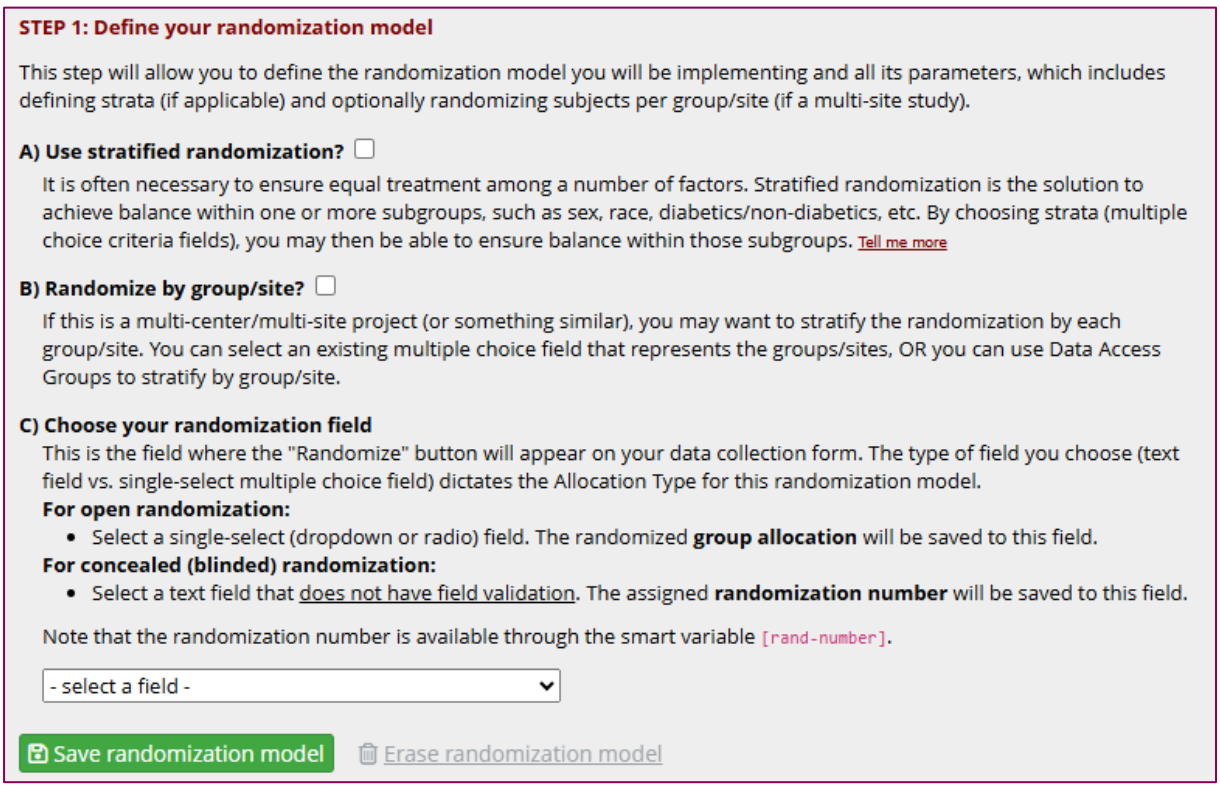
Setting up the Randomization

To set up and define the randomization, click on Add new randomization model in the *Randomization* menu (left-hand side of the screen).



Step 1: Define Randomization Model

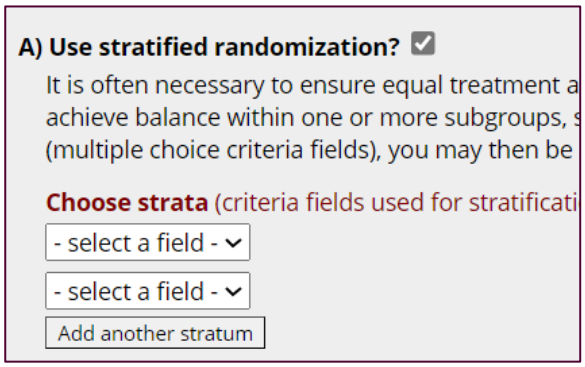
First, the parameters for the randomization module need to be set up.



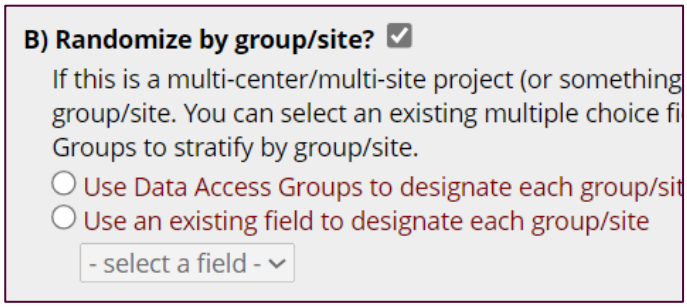
You can choose stratified randomization or randomization by group/site.

A) Stratified randomization

Stratified randomization aims to balance different randomization groups by taking into account specific variables (e.g. age). How to balance the groups is determined in the allocation table by adding one or more stratification variables from your instruments. Increasing the number of stratification variables will lead to fewer subjects per stratum.

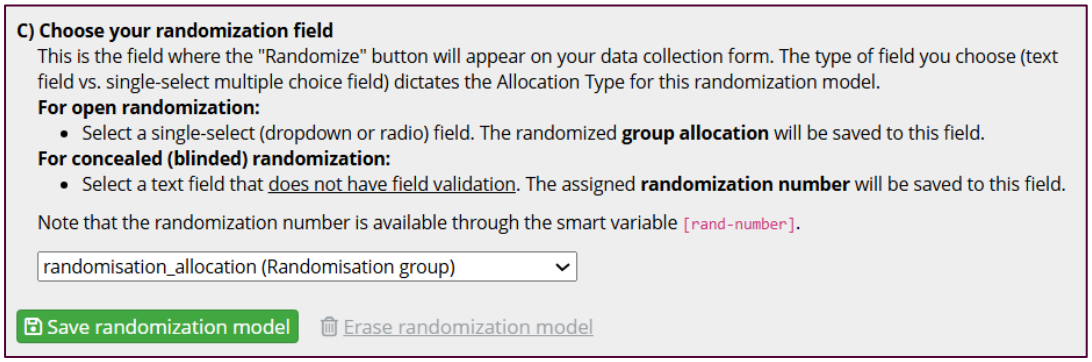


B) Randomize by group/site

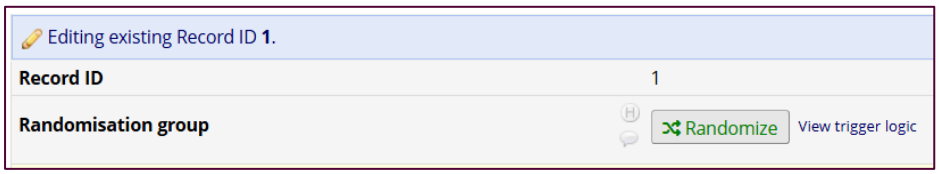


This option allows you to randomize by either Data Access Groups or by a REDCap drop-down list of different sites (found in your instruments). This option is useful in, for example, multicentre studies.

In addition, you have to **choose a randomization field (C)** in one of your forms/instruments. This is the field where the allocated randomization group (treatment/control/etc.) will be saved; it is also where the "Randomize" button will appear on your data collection form when creating new records via *Add/Edit Records*.



(Note that the "Randomize" button will not appear in *Designer* even after setting up and saving your randomization model; to see the randomize button, you need to choose a record and open the relevant instrument for data entry.)

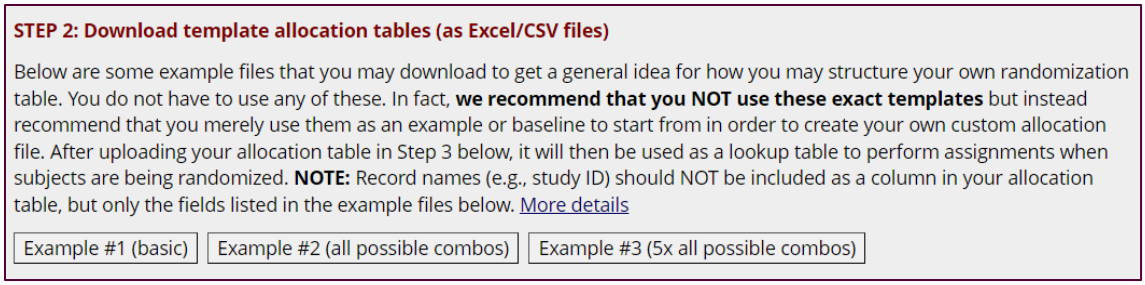


Finally, you can choose whether the randomization field displays the group allocation (see "For open randomization" under Step 1 C) or if a randomization number is saved instead (see "For concealed (blinded) randomization").

Don't forget to click on "save randomization model" when you are done defining your model.

Step 2: Create Allocation Tables

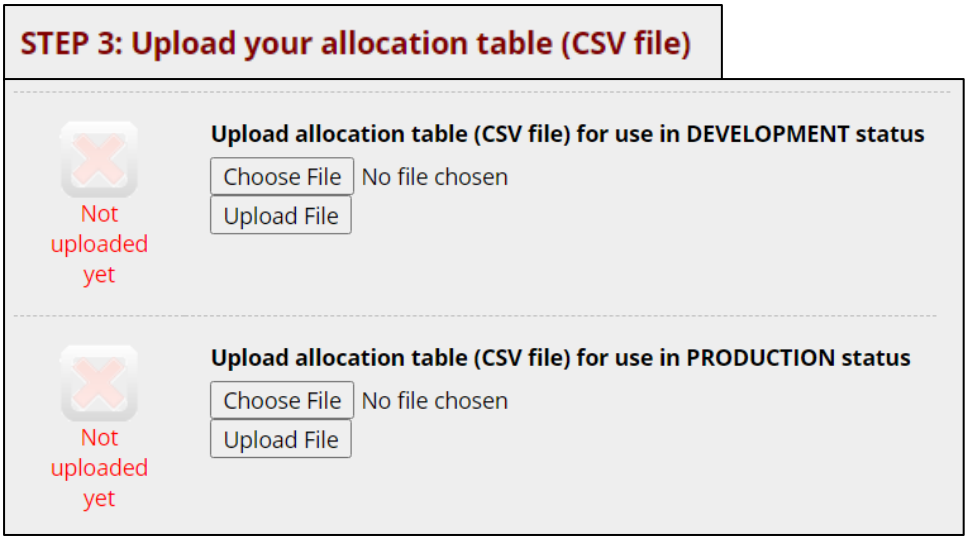
Once you defined your randomization and saved the model, REDCap generates several different template allocation tables which contain the raw coded values for the fields you included in step 1.



Choose the table that best suits your project and start adding your allocations.
Note: Ideally, this step should be performed by a statistician while the rest of the study team remains blind to the allocations.

Step 3: Upload Allocation Tables

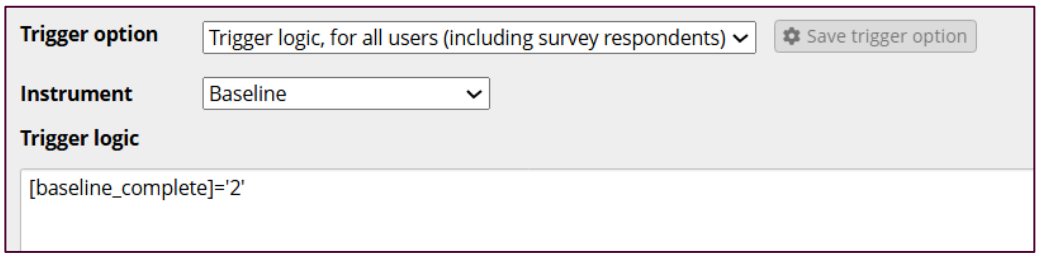
Once both allocation tables have been created, you may import them back into REDCap and start testing your randomization module.



The first table is for testing your project (Development) and should not be the same as the one you will use to recruit actual participants. Make sure to test your randomization module while the project is in Development by adding test records.

Step 4: Automatic Triggering Option

Randomization can be automated by defining logic to trigger randomization, for example, when a certain form or survey is saved in REDCap.



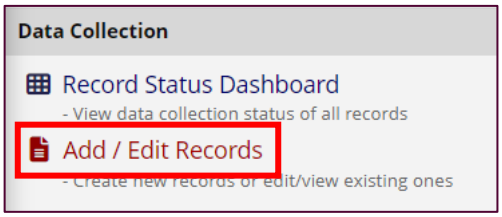
1. Decide who can trigger automatic randomization under “Trigger option” (choose between manual trigger, trigger logic for users with permission in user rights, or trigger logic for everyone including survey participants).
2. Choose which instrument should be the trigger under “Instrument” (the randomization field can be placed in the same or a separate instrument; if placed in a survey, the randomization field can be hidden from participants)
3. Add logic to determine exactly when randomization is triggered/activated under “Trigger logic”.

Possible applications of auto-randomization:

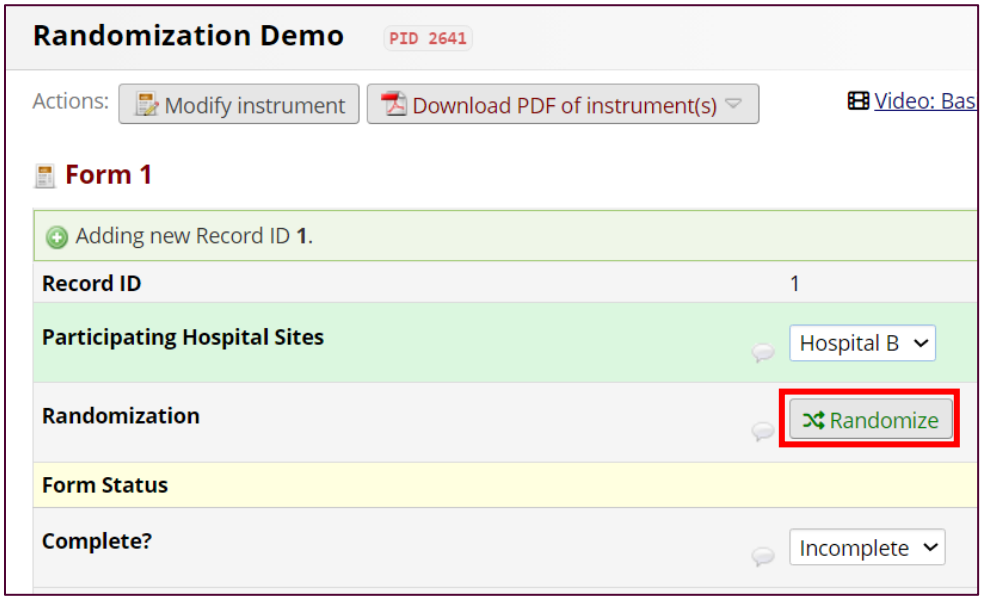
- Study participants can complete an initial REDCap survey, automatically be randomized, and then sent on to further surveys based on their allocation group, all without a REDCap user having to get involved.

Manually Randomizing a Record

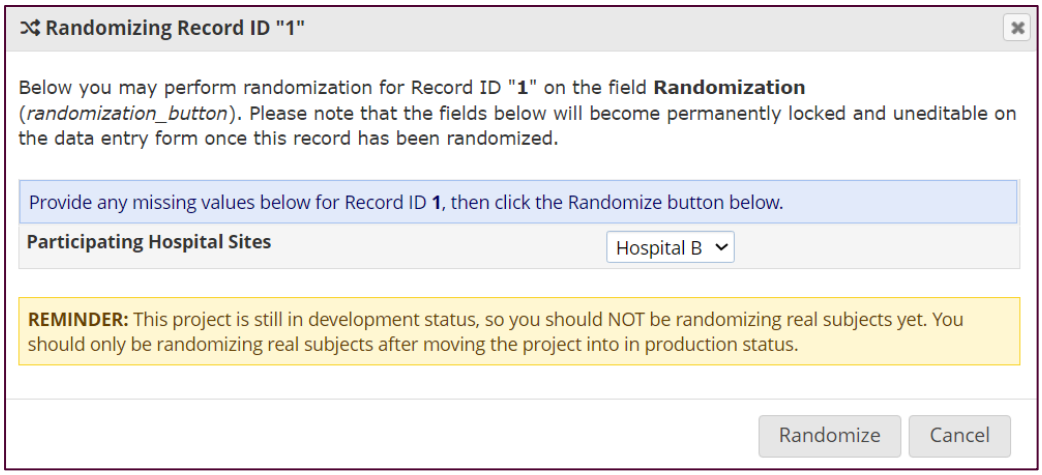
Any user who has been given "randomize" user rights is now able to create a new record and randomize participants.



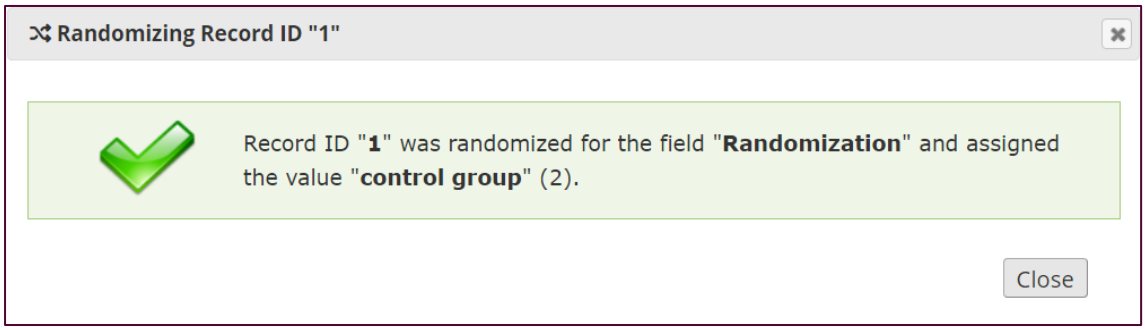
The chosen randomization field (Step 1, C) will now display a "Randomize" button in the relevant instrument/form when creating a new record.



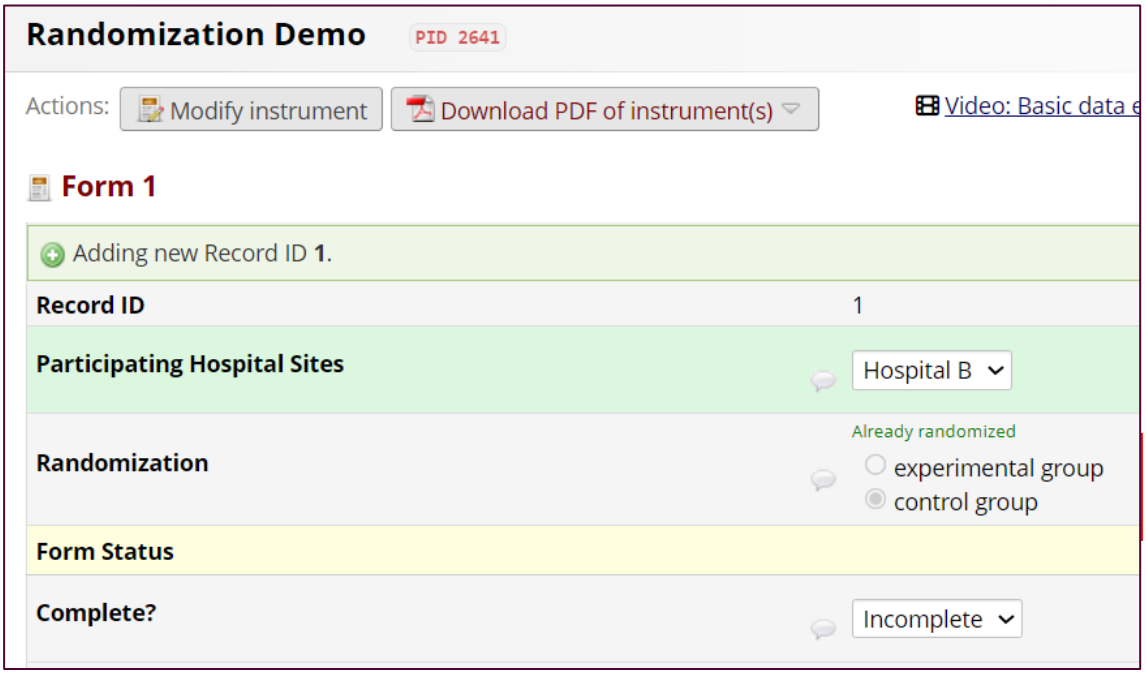
When clicking on the "Randomize" button, a pop-up window will appear where the user can double-check relevant parameters and confirm the randomization.



After randomizing a record, another pop-up window appears showing which group the participant was assigned to.



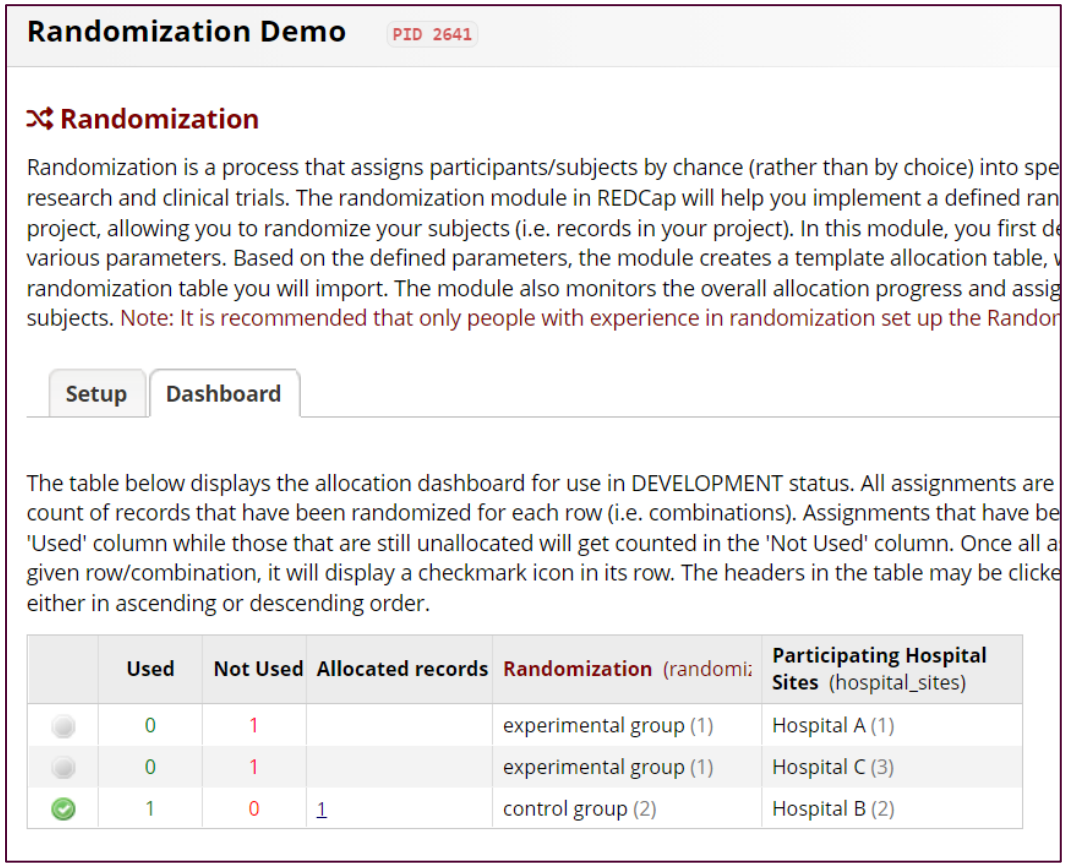
In addition, the randomization is locked into the randomization field and the field becomes read-only and can no longer be changed.



If automatic randomization is enabled, it is still possible to click on the "Randomize" button instead if the randomization has not yet been triggered.

The Allocation Dashboard

The *Dashboard* tab in the "Randomization" menu shows a list of all available and used allocations based on the allocation table you uploaded.



Here, you can get a snapshot of the status of your allocation table. REDCap groups allocations of the same type (with the same combinations of parameters) together in one row:

- "Used": shows how many allocations of this type have already been assigned.
- "Not Used": shows how many allocations of this type have not yet been assigned.
- "Allocated records": shows which records have been assigned to this allocation group.
- Second to last column (here "Randomization"): shows to which randomization group records with this type of allocation were assigned to (based on the randomization field you set in Step 1 above).
- Last column (here "Participating Hospital Sites"): shows which group/site this type of allocation is part of (based on the field you defined in Step 1 above).

- First column on the left: shows a green checkmark when all allocations from that row/allocation group have been assigned.

It is possible to click on the headers in the table to change the order of the displayed allocation groups.

Tips & Best Practices

Randomization can only be set up while the project is in *Development*. Once a project is moved to *Production*, the randomization setup tab is locked, and randomization settings can no longer be modified.

Make sure to include more allocations in your table than you think you will need to accommodate, for example, drop-outs and to enable the possibility to randomize additional participants.

Always prepare two different allocation tables. One to test your project (*Development*) and one for the actual recruitment of participants (*Production*). These two allocation tables must not be the same.

Ideally, the allocation table should be created by a statistician. The rest of the study team should remain blinded to the allocations.

Remember to limit access to randomization features in the *User Rights* section.

Make sure to test your randomization module before moving your project to *Production* and starting recruitment.

REDCap follows the allocation table from top to bottom, choosing the next possible match in the table based on the defined criteria.

If you want to use the smart variable [rand-number], you must use the concealed (blinded) randomization field type (Step 1C). This could be a useful feature if you, for example, want to inform your survey participant of which group they've been assigned to.