

VEJLEDNING

Randomisering i REDCap

Denne vejledning beskriver, hvordan randomiseringsmodulet anvendes i REDCap. Modulet er særligt velegnet til:

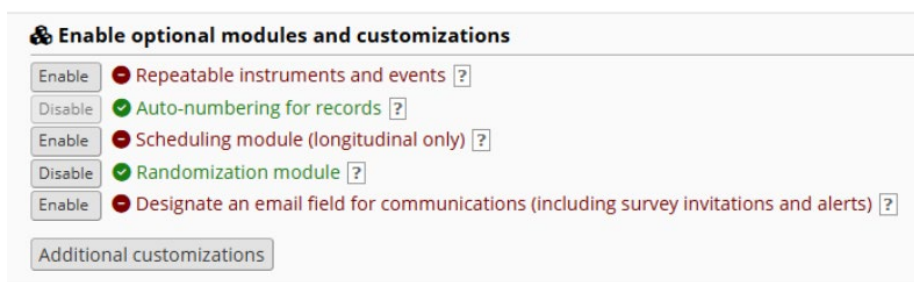
- Ublindede studier (både personale og patient kender tildelt gruppe)
- Enkeltblindede studier (kun personale kender tildelt gruppe)

Bemærk: Til dobbeltblindede studier anbefales alternative metoder, da REDCap ikke understøtter dette effektivt. En mulig løsning kan være, at en betroet medarbejder foretager randomiseringen, som er placeret i et instrument, der kun kan tilgås af den betroede medarbejder.

I REDCap er randomisering baseret på en uploadet allokalationstabel. Denne allokalationstabel kan op sættes med blokstørrelser som det ønskes inklusiv vægtede allokalationer. Der kan desuden stratificeres på et vilkårligt antal variable.

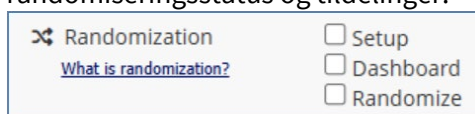
Aktiveringen, brugerrettigheder og ansvar:

Brugere med **“Project Design and Setup”**-rettigheden kan aktivere randomiseringsmodulet via **Project Setup**.



Herefter kan man se og tildele rettigheder til randomisering under **User Rights**, hvorefter selve modulet er tilgængeligt i menuen i venstre side under ”Applications”

- **Setup:** Oprette og konfigurere modulet, samt uploade allokalationstabel.
- **Randomize:** Udføre randomisering af deltager.
- **Dashboard:** Overvåge randomiseringsstatus og tildelinger.



Opsætning af randomisering

Step 1: Definer din randomiseringsmodel

Modellen bør være beskrevet i en protokol og skal afklares med en statistiker eller Principal Investigator.

Opret et **"Multiple Choice (Single Answer)"**-felt (Drop-down eller Radio Buttons)
Eksempel:

- 1, Behandling A
- 2, Behandling B
- 3, Kontrol

Du kan for eksempel stratificere på variable såsom køn, aldersgrupper eller sygdomshistorik og der kan stratificeres på DAG/site.

Nedenfor ses randomiseringsmodellen, hvor variabelen "Gender" er valgt som strata og variabelen "Randomisering" er valgt som randomiseringsfelt.

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).

NOTE: This section is currently locked and uneditable because the randomization setup process has already been completed. If you wish to modify the randomization setup below, you will need to click the Erase Randomization Model button below.

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. [Tell me more](#)

Choose strata (criteria fields used for stratification; may specify up to 14 multiple choice fields)

gender (Gender Male Female) ▼ for Whols (Arm 1: Armon) ▼

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.

☒ Use Data Access Groups to designate each group/site (3 groups currently exist)

☐ Use an existing field to designate each group/site

- select a field - ▼ for ▼

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.

rando (Randomisering) ▼ for Whols (Arm 1: Armon) ▼

Step 2: Opret alloktionstabel

Når modellen er gemt, kan en skabelon for alloktionstabellen hentes fra REDCap. Skabelonen skal IKKE bruges direkte i studiet. Den kan bruges til at se strukturen af alloktionstabellen til det givne projekt.

STEP 2: Download template allocation tables (as Excel/CSV files)

Below are some example files that you may download to get a general idea for how you may structure your own randomization table. You do not have to use any of these. In fact, **we recommend that you NOT use these exact templates** but instead recommend that you merely use them as an example or baseline to start from in order to create your own custom allocation file. After uploading your allocation table in Step 3 below, it will then be used as a lookup table to perform assignments when subjects are being randomized. **NOTE:** 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 below. [More details](#)

Example #1 (basic)

Example #2 (all possible combos)

Example #3 (5x all possible combos)

REDCap udfører ikke en randomisering selv, men allokterer patienter baseret på rækkefølgen i den uploadede liste, som derfor skal være randomiseret.

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

Allokationstabellen, der skal indlæses i REDCap i det pågældende tilfælde, skal bestå af de første 2 kolonner, hvor den første kolonne refererer til variabelnavnet i det felt der er opsat til randomiseringen og den anden kolonne referer til stratificeringskolonnen.

Hjælp til oprettelse af alloktionstabel

Hvis du ikke selv kan lave en alloktionstabellen, kan du kontakte administratorteamet på red-cap@rn.dk. Herefter vil en REDCap-administrator hjælpe med at lave tabellerne eller, ved avanceret modeller, henvise dig til statistikhjælp.

Step 3: Upload din alloktionstabel

Hver projektfase (*development og production*) kræver sin egen unikke tabel.

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 kept 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.



Not
uploaded
yet

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

Vælg fil Der er ikke valgt nogen fil

Upload File



Not
uploaded
yet

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

Vælg fil Der er ikke valgt nogen fil

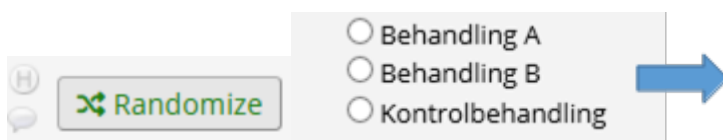
Upload File

Allokationstabellen kan ikke bruges til begge, da REDCap kontrollerer, at de ikke er ens.

❗ ERROR: Duplicate allocation table!

The allocation table you just uploaded was not accepted or saved because it matches the other allocation table that has already been previously uploaded. Please be aware that the allocation table used in Development status cannot be exactly the same as the allocation table used in Production status. Please modify your allocation table and upload it again.

Efter upload bliver randomiseringsmodulet aktivt og viser nu en knap til randomisering i stedet for valgmulighederne.



Step 4: Gennemførelse af randomisering

Når du trykker på Randomize-knappen for en rekord, vil en pop-op boks åbne. Her kan du trykke **randomiser**, samt tjekke eller udfylde strata og DAGs for denne rekord.

Randomiseringsfeltet er nu "read-only" og kan **IKKE** ændres af nogen, ligesom de variable som randomiseringen er baseret på heller ikke kan ændres.

En REDCap-administrator kan uploade yderligere allokeringer, når projektet er i produktion, hvis der bliver brug for flere.

Tips til randomisering i REDCap

- **Lav alloktionstabellen længere**, end du regner med at bruge.
- **Brug 'Branching Logic'**, så kun egnede deltagere kan randomiseres.
- **Placer randomiseringsfeltet i et separat instrument**, hvis kun udvalgte brugere skal kunne randomisere.
- **Brug blokrandomisering**, for at fjerne risikoen for en skæv fordeling.