

# Randomisation

## What is Randomisation?

Randomisation is where there are at least two different groups in a trial, and participants are allocated to into one or another group at random (or seemingly at random).

Certain details about the participant (such as age, gender or the stage of disease) are identified first and this is used to ensure that the different groups in a trial are as similar as possible, that they are balanced.

## Why use Randomisation?

Randomisation is used to prevent bias, it provides an independent means of allocation.

## Randomisation at Keele CTU

As outlined above, randomisation is a hugely important function within a trial. It can also be quite a complex requirement. Here at Keele CTU we have developed and use a validated centralised service called RAND-L (RANDomisation List Generator) which performs the required randomisation. RAND-L was developed as an application programming interface (API) that developers within the CTU can use to interface trial management software with the chosen randomisation sequence. All the necessary randomisation requirements of the trial (e.g. number of arms, number of strata) are entered into RAND-L, which then generates the required randomisation set which is stored separately and securely.

You will recall that within yesterday's presentation on Electronic Data Capture (EDC), we provided you with a brief insight into our Study Management Web Applications. With the addition of RAND-L, Keele CTU has the power to seamlessly integrate the randomisation process. Randomisations can therefore be carried out online, at any time and by both internal and external users (providing the required access permissions are in place).

RAND-L is a unique service in that it offers the ability to interface with open source software through its API and allows its end users to generate sets of sequences as required, whether that be for testing purposes or for actual use.

Below are screenshots of what is used by the Keele CTU staff to undertake randomisation of a participant, using the Study Management Application and RAND-L:

Example of the Randomisation process within Keele CTU Study Management Application using RAND-L API

**Randomise**  
Study ID 32136

**Randomisation details**

**Filling in randomisation confirmation**  
Please check that you've selected the correct participant and that ALL PAPERWORK is accounted for and fully completed before proceeding with randomisation. Once a participant is randomised, this cannot be undone as they will have taken the next available slot in the chosen sequence.

Full name: Princess Khaliah Ratzliff  
Date of birth: 20 March 1989  
Postcode: CW1 1WE  
Randomiser: Jo Smith  
Randomised on behalf of: [User Selection]

Patient's knee buckled or given way in the past 3 months (Q36 in Baseline Questionnaire): Yes [User Selection]

Predominant compartmental distribution of knee OA (see Initial Treatment Session CRF, QAS): (A) No Predominant Compartment [User Selection]

Consented to the study & eligible for randomisation  
 Baseline questionnaire has been completed and checked for required completeness

**Randomise This Participant**

**Step 1:** Select the 'randomiser' from the list of registered users

**Step 2:** Select the relevant options from the required strata

**Step 3:** Confirm with the randomiser that the necessary items are complete (prior to randomising)

**Step 4:** Click 'Randomise This Participant'

Example of the subsequent Randomisation Outcome screen  
This displays to the user which arm/Treatment group the participant has been randomised to

**Randomisation Outcome**

**Study ID 26 has been randomised!**  
The following participant has been successfully randomised.

Date of randomisation:	18/05/2022 14:33:02
Randomised by:	Steven Harper
Study ID:	26
Participant date of birth:	20 January 1979
<b>Treatment Group:</b>	<b>Best Primary Care PLSB Block</b>