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

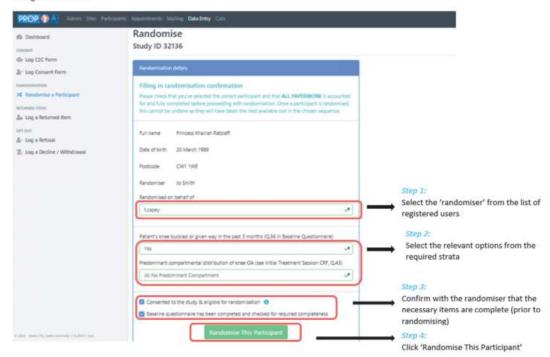
As outlined above, randomisation is a hugely important function within a trial. It can also be quite a complex requirement. Here at Keele CTU we have developed and use a validated centralised service called RAND-L (RANDomisation List Generator) which performs the required randomisation. RAND-L was developed 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



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

