

Randomisation Services:

The KCTU manages a bespoke online randomisation system, supporting

- simple randomisation
- block randomisation
- stratified block randomisation
- minimisation

Packages:

The cost calculation of the randomisation service is based on the sample size and the complexity of the study team requirements. The system is online and can be accessed 24 hours a day. Researchers within the study team log in, enter key information about the participant, and the randomisation allocation occurs instantly. Confirmation emails are generated automatically and sent to relevant personnel in the study team.

Researchers can be assigned the ability to randomise participants or they can be assigned an 'observer' role, where they are copied into randomisation confirmation emails. All researchers, whether 'randomisers' or 'observers' can be kept blind to treatment allocation where appropriate, with pharmacists or therapists receiving confirmation emails with treatment allocation information. Multiple stratification or minimisation factors may be programmed into the system. Test data is generated before the study begins, to check balance across stratification factors. The system can be programmed to perform validation checks, such as checking for duplicate Participant Identification Numbers and preventing randomisation from proceeding in such cases.

In medicinal trials, the active and placebo unique treatment pack numbers, batch numbers and expiry dates can be programmed into the system, with the system recording packs delivered to specific site pharmacies and only allocating medication packs that are available in that site to participants randomised there. The system can also be programmed to generate a schedule of each participants visit timeline for the entire study, to be sent within the randomisation email. A standard feature of all service levels is the ability to download automatically generated recruitment graphs of overall recruitment against target recruitment.

Costs:

Bronze service:

Sample size x £6.50
Minimum charge £650
Maximum charge £1,030
Two users (randomisers or observers)

One email confirmation in a blinded format (to outcome assessor)
One email confirmation in an unblinded format (to therapist or pharmacist)
No visit window schedule
No link to medicinal treatment pack numbers
Up to one dichotomous stratification factor allowed

Silver service:

Sample size x £8.00
Minimum charge £800
Maximum charge £1,545
Up to ten randomisers or observers
Up to five study sites

Site specific email confirmations in a blinded format (to outcome assessors)
Site specific email confirmations in an unblinded format (to therapists or pharmacists)
No visit window schedule
No link to medicinal treatment pack numbers
Up to three dichotomous stratification factors allowed

Gold service:

Sample size x £11.00
Minimum charge £1,100
Maximum charge £2,575
Up to twenty randomisers or observers
Up to ten study sites

Site specific email confirmations in a blinded format (to outcome assessors)
Site specific email confirmations in an unblinded format (to therapists or pharmacists)
Schedule of patient visit window dates generated at randomisation (e.g. 3 months +/- 7 days)
Unlimited stratification factors allowed
No link to medicinal treatment pack numbers

Platinum service:

Sample size x £16.00
Minimum charge £1,600
Maximum charge £5,150
Unlimited requestors
Unlimited number of study sites

Site specific email confirmations in a blinded format (to outcome assessors)
Site specific email confirmation in an unblinded format (to therapists or pharmacists)
Schedule of patient visit window dates generated at randomisation (e.g. 3 months +/- 7 days)
Unlimited stratification factors allowed
Randomisation linked to blinded treatment pack numbers
Alerts generated when blinded study medication supplied running low at site in either arm

To request a formal quote please complete support request form online www.ctu.co.uk.