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 participant’s 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 link to medicinal treatment pack numbers
- No visit window schedule
- 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)
- No link to medicinal treatment pack numbers
- Unlimited stratification factors allowed

**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](http://www.ctu.co.uk).