

Study Management



Study Management Support

The BCTU can provide the following support for running clinical studies:

Independent Randomisation Service

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- Paper-based telephone randomisation available Monday-Friday, 9am to 5pm
- Basic computerised telephone randomisation available Monday-Friday, 9am to 5pm
- Internet computerised randomisation available 24/7.

Further information on our randomisation service and related costs is available on request.

Study Management Models (subject to capacity)

BCTU offers two levels of study management support:

Full Study Management (preferred model) : Where study co-ordination, randomisation, programming and statistical support is all provided by BCTU. The BCTU has considerable expertise in running clinical studies and has internal management systems that facilitate study management and monitoring, and thereby provides a valuable resource for running clinical studies.

Hub and Spoke : Where the researcher manages and conducts the clinical study with the appropriate staff at their own centre, but programming and statistical support is provided by BCTU. We can work with external researchers in a collaborative partnership, where primary responsibility for the management and conduct of the study lies with the external researcher, but the BCTU has joint responsibility for the design and analysis.

For both of the above models it would be expected that:

- At least one member of the BCTU is named as a co-applicant on the grant application;
- Appropriate costs are included in the grant application;
- A collaborative partnership is formalised by a written agreement determining the scope of the work provided by the BCTU and the resources coming to the BCTU for the work to be undertaken.

Database System Design/Development (subject to capacity)

BCTU can provide advice on database system development and IT needs for clinical studies. We can also (subject to capacity) provide IT and database support for the study. This may include a randomisation service (see above), database system development and maintenance and/or storage of electronic data. Costs for programming support should be included in the grant application.

Statistical Analysis (subject to capacity)

BCTU can also provide statistical support for studies, and costs for this service should be included in the grant application. Statistical support will generally only be provided when IT and database support for the study is also being provided by BCTU.

Statistical analysis of interim or final datasets from clinical studies that were not run by or associated with the Unit are not undertaken. Nor will BCTU undertake statistical analyses, for health professionals who are undertaking a clinical study or systematic review as part of a higher degree, where it would be expected that the statistical analysis and interpretation of the data should be done by themselves.

Requesting Study Management Support from BCTU

BCTU can provide support for running clinical studies such as independent randomisation, study co-ordination, provision of study specific database systems and/or statistical analysis. If you are requiring some level of study management support, then your study will need to be reviewed by BCTU's New Business Group to determine whether your study fits into any of our disease portfolios and whether the Unit has the capacity to help. This group meets every fortnight.

Please note that with NIHR funding streams now requiring that clinical trials are run through UKCRC registered trials units, BCTU has seen a large increase in requests for study management support. Unfortunately, BCTU does not have unlimited capacity to provide this support for every request, and therefore we must prioritise those projects that fit in with the Unit's strategic direction and speciality fields. These are reviewed annually, and currently consist of women's health, neurodegenerative diseases, renal disease, coloproctology, surgical studies, burns, trauma and critical care. This allows the Unit to consolidate expertise in particular disease areas, but retain some flexibility to be able to adapt to new developments and initiatives.

Where BCTU agree to provide such support, the appropriate costs must be included in the grant application.

