

Statistical input into research is vital to ensure that data is robustly collected and analysed, thereby providing reliable results which are publishable in high impact journals. King's CTU provides three levels of statistical collaboration.

Standard Collaboration (including pilot studies):

This level of collaboration is most useful for UK based single centre or multi-centre studies with a standard size database, i.e. where the number of variables and the sample size are both typically <500. In general, there are less than 10 centres **and** centres are teaching institutions/ experienced in research, or are within sufficient proximity such that central statistical monitoring is not deemed to be required, as on-site monitoring visits can feasibly be undertaken.

Resource required:

- 25% Junior statistician to be costed into the grant application
- 5% Senior statistician supervision to be costed into the grant application

Advanced Collaboration:

This level of collaboration is most useful for larger trials and databases, i.e. where either the number of variables and/or the sample size are typically >500. This includes multicentre and multinational studies and may include research naïve centres **or** centres not based within sufficient proximity such that on-site monitoring visits can not feasibly be undertaken or where it is more cost efficient to conduct increased central statistical monitoring and decreased on site monitoring.

Resource required:

- 50% Junior statistician to be costed into the grant application
- 5-10% Senior statistician supervision to be costed into the grant application

Feasibility Collaboration:

This level of collaboration is most useful for feasibility or proof of concept studies. It is anticipated that no DMC reports will be required as part of this package, (if this is required, provision will be 1 report /year detailing AE's & recruitment)

Resource required:

The level of involvement required for this type of study is variable and the resource stated below is for reference only, each study will be reviewed on a case-by-case basis to ensure that an appropriate costing is provided.

- 10% -15% Junior Statistician to be costed into the grant application
- 5% - 10% Senior Statistician to be costed into the grant application

Note: definitions for standard and large databases are indications only and should be reviewed on a case by case basis

Details of the levels of collaboration:

	Standard	Advanced	Feasibility
Develop the design for a clinical trial or other study including assisting in the preparation of the study protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Respond to reviewer's comments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Prepare sample size calculation	<input type="checkbox"/>	<input type="checkbox"/>	(optional)
Advise on randomisation method	<input type="checkbox"/>	<input type="checkbox"/>	
Advise on the preparation of case report forms (CRFs)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Prepare DMEC/TSC reports (~1-2/Year)	<input type="checkbox"/>	<input type="checkbox"/>	(optional)
Provide central statistical monitoring (requiring additional data exports approx. every 1-2 months)		<input type="checkbox"/>	
Write the statistical analysis plan in collaboration with the CI	<input type="checkbox"/>	<input type="checkbox"/>	
Attend a proportion of TMG meetings	<input type="checkbox"/>		(optional)
Attend regular TMG meetings		<input type="checkbox"/>	
Prepare code for primary analysis (primary publication)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Prepare code for one secondary publication (e.g. mediation analysis)		<input type="checkbox"/>	
Contribution to production of reports to funders (creating CONSORT & Recruitment charts)		<input type="checkbox"/>	
Assume standard size dataset with moderate number of secondary outcomes	<input type="checkbox"/>		
May analyse large dataset, and include mediation and/or moderation analyses		<input type="checkbox"/>	
Conduct primary analysis for primary paper (Inc. primary analysis code checks)	<input type="checkbox"/>	<input type="checkbox"/>	(descriptive only)
Conduct secondary analysis for one secondary paper		<input type="checkbox"/>	
Prepare statistical report and contribute to writing of the primary paper	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Contribute to writing of one secondary paper		<input type="checkbox"/>	
Advise on the development of study to a definitive trial			<input type="checkbox"/>

To request a formal quote (including Standard and Advanced collaborations) please complete support request form online www.ctu.co.uk