



Please contact us with any questions, or to discuss your trial idea

[ECTU-new.proposals@ed.ac.uk](mailto:ECTU-new.proposals@ed.ac.uk)

or new project support request

	Grant Application	Project Planning	Project Set-Up	Project Execution	Project Execution
	Grant Application	Project Planning (before start of grant)	Project Set-Up (after start of grant)	Recruitment & Data Collection	Close-Out & Reporting
<b>Research Development &amp; Trial Planning</b>	<ul style="list-style-type: none"> <li>• Coordination of proposal development</li> <li>• Project Gantt chart</li> <li>• Editorial support</li> <li>• Justification of resources</li> <li>• ECTU resource assessment</li> <li>• Letter of Support</li> </ul>	<ul style="list-style-type: none"> <li>• Support drafting protocol &amp; key documents for Sponsor Risk Assessment</li> <li>• Support identification of required approvals, contracts and supply agreements</li> <li>• Scope data management and programming requirements</li> <li>• Support identification and mitigation of risks for project delivery</li> <li>• Liaise with internal and external stakeholders to prepare study for scheduled start</li> <li>• Prepare hand-over to ECTU project execution teams</li> </ul>	<ul style="list-style-type: none"> <li>• Support handover to project execution teams</li> </ul>	<ul style="list-style-type: none"> <li>• Finance support for substantive project changes (requesting reconciliations, coordinating extension costings)</li> </ul>	
<b>Methodology &amp; Statistics</b>	<ul style="list-style-type: none"> <li>• Robust methodology</li> <li>• Sample size</li> <li>• Proposal development</li> <li>• Resource assessment</li> <li>• Funding application</li> </ul>	<ul style="list-style-type: none"> <li>• Protocol drafting</li> <li>• Identification of oversight committee members</li> </ul>	<ul style="list-style-type: none"> <li>• Protocol completion</li> <li>• Documents (CRFs)</li> <li>• Advice on randomisation system</li> <li>• Draft TSC/DMC report</li> <li>• Table of Responsibilities</li> </ul>	<ul style="list-style-type: none"> <li>• Statistics master file</li> <li>• Statistical analysis plan</li> <li>• DMC report</li> <li>• Protocol amendments</li> <li>• Advice to TSC and TMG</li> </ul>	<ul style="list-style-type: none"> <li>• Analyses</li> <li>• Reporting</li> <li>• Dissemination</li> <li>• Data sharing</li> </ul>
<b>Health Economics</b>	<ul style="list-style-type: none"> <li>• Robust methodology</li> <li>• Proposal development</li> <li>• Resource assessment</li> <li>• Funding application</li> </ul>	<ul style="list-style-type: none"> <li>• Protocol drafting</li> </ul>	<ul style="list-style-type: none"> <li>• Protocol completion</li> <li>• Documents (CRFs)</li> <li>• Table of Responsibilities</li> </ul>	<ul style="list-style-type: none"> <li>• Health economic analysis plan</li> <li>• Health economic modelling/ design/ parameter resourcing</li> </ul>	<ul style="list-style-type: none"> <li>• Analyses</li> <li>• Reporting</li> <li>• Dissemination</li> </ul>
<b>Trial Management</b>	<ul style="list-style-type: none"> <li>• Proposal development</li> <li>• Resource assessment</li> </ul>		<ul style="list-style-type: none"> <li>• Finalise protocol and documents</li> <li>• Sponsor Risk Assessment</li> <li>• Regulatory approvals</li> <li>• Table of Responsibilities</li> <li>• Support CRF development</li> <li>• Vendor assessments/audits</li> <li>• Caldicott/IT security appls</li> <li>• R&amp;D submissions/approvals</li> <li>• Site feasibility Qs</li> <li>• Organisation and conduct of SIVs</li> </ul>	<ul style="list-style-type: none"> <li>• Maintain TMF</li> <li>• Support to sites</li> <li>• Progress reporting</li> <li>• Protocol and document amendments</li> <li>• Finances</li> <li>• TMG, TSC, DMC mtgs</li> </ul>	<ul style="list-style-type: none"> <li>• Supporting Analyses</li> <li>• Reporting</li> <li>• Dissemination</li> <li>• Archiving of TMF</li> </ul>
<b>Data Management &amp; Programming</b>	<ul style="list-style-type: none"> <li>• Proposal development</li> <li>• Resource assessment</li> </ul>		<ul style="list-style-type: none"> <li>• Support CRF development</li> <li>• Table of Responsibilities</li> <li>• Build study database</li> <li>• Build randomisation system</li> <li>• Data Management Plan</li> </ul>	<ul style="list-style-type: none"> <li>• Reports</li> <li>• QC checking &amp; audit</li> <li>• Protocol amendments</li> <li>• Implementation of data management plan</li> </ul>	<ul style="list-style-type: none"> <li>• Database lock</li> <li>• Archiving of electronic data</li> <li>• Data sharing</li> </ul>
<b>Quality Assurance</b>	<ul style="list-style-type: none"> <li>• Gap analysis</li> </ul>	<ul style="list-style-type: none"> <li>• Gap analysis</li> </ul>	<ul style="list-style-type: none"> <li>• Identify relevant SOPs</li> <li>• Table of Responsibilities</li> </ul>	<ul style="list-style-type: none"> <li>• Monitor SOP compliance</li> <li>• Support audit / inspections as required</li> </ul>	<ul style="list-style-type: none"> <li>• Monitor SOP compliance</li> <li>• Support audit / inspections as required</li> </ul>