

This unit receives National Institute for Health Research CTU Support Funding. This funding has been awarded to support the unit in developing and supporting NIHR research.

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Q-034 - KCTU Support Request Form

Please complete this form and return to ctu@kcl.ac.uk or post to KCTU Administrator, KCTU, Room M2.06, PO64, Institute of Psychiatry, 16 De Crespigny Park, London SE5 8AF

Please read leaflets at www.ctu.co.uk before completing this form.

Requests for support will be considered monthly by the KCTU management group. Please ensure requests are submitted by the 20th – any forms received after that will be considered the following month.

Q1. Main point of Contact	Name	
	Tel no	
	Email	
	Preferred contact time/day	

Q2. Is the planned project an interventional trial?	<input type="checkbox"/> Yes	<i>Go to Q3</i>
	<input type="checkbox"/> No	<i>Please seek alternative support unless health economic input alone needed</i>

Q3. Is the trial a (CTIMP) clinical trial of an Investigational Medicine?	<input type="checkbox"/> Yes	<i>Please visit the website (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/317952/Algot_hrim.pdf)</i>
	<input type="checkbox"/> No	

Q4. Have you already approached Research Design Service?	<input type="checkbox"/> Yes	<i>Go to Q4</i>
	<input type="checkbox"/> No	<i>Please visit the website http://www.rds.nihr.ac.uk/</i>

Q5. Is the planned project funded?	<input type="checkbox"/> No, decision on which funder to approach has not yet been made	<i>Please seek advice from the Research Design Service</i>
	<input type="checkbox"/> No, it is a one stage application process	<i>Go to Q5</i>
	<input type="checkbox"/> No, it is at the outline application stage	<i>Go to Q5</i>
	<input type="checkbox"/> No, it is at full application stage	<i>Go to Q5</i>
	<input type="checkbox"/> Yes, funding awarded and in setup stage	<i>Please provide award letter</i>
	<input type="checkbox"/> Yes, funded and patient recruitment started	<i>Please seek alternative support</i>

Q6. Submission deadline	Click here to enter a date.
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Q7. Planned grant funding	Start date	Click here to enter a date.
	End date	Click here to enter a date.

Q8. Planned start date of patient recruitment	Click here to enter a date.
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Q9. Describe disease area	
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Q10. Has a draft case for support been written?	<input type="checkbox"/> YES	<i>Please attach a copy with this form.</i>
	<input type="checkbox"/> NO	<i>Please attach an A4 PICOT summary of your study proposal. For your reference, see http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3430448/</i>

Q11. Funder	<input type="checkbox"/> NIHR HTA GRANT	
	<input type="checkbox"/> NIHR EME GRANT	
	<input type="checkbox"/> NIHR PHR GRANT	
	<input type="checkbox"/> NIHR HS&DR GRANT	
	<input type="checkbox"/> NIHR PGfAR GRANT	
	<input type="checkbox"/> NIHR RfPB GRANT	
	<input type="checkbox"/> NIHR FELLOWSHIP GRANT	
	<input type="checkbox"/> MRC DPFS GRANT	
	<input type="checkbox"/> MRC OTHER GRANT	
	<input type="checkbox"/> WELLCOME TRUST GRANT	
	<input type="checkbox"/> EUROPEAN UNION GRANT	
	<input type="checkbox"/> CHARITY GRANT	
	<input type="checkbox"/> INDUSTRY GRANT	
<input type="checkbox"/> OTHER	<i>Please specify:</i>	

Q12. Please provide funding call URL	
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Q13. Services requested	<input type="checkbox"/> Web based randomisation service
	<input type="checkbox"/> Web based trial database/eCRF system (InferMed MACRO)
	<input type="checkbox"/> Operational Support
	<input type="checkbox"/> Data manager
	<input type="checkbox"/> Trial statistician
	<input type="checkbox"/> Trial manager
	<input type="checkbox"/> Health Economist
	<input type="checkbox"/> Pharmacy IMP management support
	<input type="checkbox"/> Qualitative Social Scientist

Q14. Full trial title	
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Q15. Trial acronym	
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Q16. Will patient recruitment be:	<input type="checkbox"/> UK Single Site
	<input type="checkbox"/> UK Multicentre
	<input type="checkbox"/> Multinational (including European sites only)
	<input type="checkbox"/> Multinational (including non-European Sites)

Q17. Details of trial Chief Investigator / lead applicant (provide both if different)	Chief Investigator name	
	Chief Investigator email	
	Chief Investigator phone	
	Lead Applicant (if different) name	
	Lead Applicant email	
	Lead Applicant phone	

Q18. Details of person collating the costs	Name	
	Email	
	Phone	

Q19. Date which costing is required by	Click here to enter a date.
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Q20. Substantive employer of the Chief Investigator	<input type="checkbox"/> KCL -- go to Q20a.	<input type="checkbox"/> SLaM -- go to Q20b.
	<input type="checkbox"/> KCH -- go to Q20b.	<input type="checkbox"/> GSTT -- go to Q20b.
	<input type="checkbox"/> OTHER	<i>Please specify & go to Q21:</i>

Q20a. If KCL, please specify school	<input type="checkbox"/> SoN	<input type="checkbox"/> IoPPN
	<input type="checkbox"/> FoLSM	<input type="checkbox"/> Dental Institute
	<input type="checkbox"/> OTHER	<i>Please specify:</i>

Q20b. If KCH, GSTT or SLaM, does the CI have an adjunct position at KCL?	<input type="checkbox"/> Yes – please provide authorised appointment letter (https://internal.kcl.ac.uk/hr/services/adjunct.aspx).
	<input type="checkbox"/> No

Q21. Lead NHS R&D Office	<input type="checkbox"/> GSTT	<input type="checkbox"/> KCH
	<input type="checkbox"/> SLaM	<input type="checkbox"/> KCL
	<input type="checkbox"/> OTHER	<i>Please specify:</i>

Q21a. Sponsor (tick all if co-sponsored)	<input type="checkbox"/> GSTT	<input type="checkbox"/> KCH
	<input type="checkbox"/> SLaM	<input type="checkbox"/> KCL
	<input type="checkbox"/> OTHER	<i>Please specify:</i>

Q22. Is this an adult or paediatric Study?	<input type="checkbox"/> Adult	<input type="checkbox"/> Paediatric
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Q23. Is this a mental health trial?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
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Q24. Is this a nurse led trial?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
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Q25. Please provide names of any senior KCTU staff members who have provisionally agreed to be co-applicants on this grant, if any:	<input type="checkbox"/> Peter Sasieni (KCTU Statistics)
	<input type="checkbox"/> Andrew Pickles (IOPPN Statistics)
	<input type="checkbox"/> Kimberley Goldsmith (IOPPN Statistics)
	<input type="checkbox"/> Sabine Landau (IOPPN Statistics)
	<input type="checkbox"/> Daniel Stahl (IOPPN Statistics)
	<input type="checkbox"/> Ben Carter (IOPPN Statistics)
	<input type="checkbox"/> Richard Emsley (IOPPN Statistics)
	<input type="checkbox"/> Janet Peacock (FOLSM Statistics)

	<input type="checkbox"/> Yanzhong Wang (FOLSM Statistics)
	<input type="checkbox"/> Fiona Reid (FOLSM Statistics)
	<input type="checkbox"/> Abdel Douiri (FOLSM Statistics)
	<input type="checkbox"/> Catey Bunce (FOLSM Statistics)
	<input type="checkbox"/> Salma Ayis (FOLSM Statistics)
	<input type="checkbox"/> Iftekhar Khan (Dental Statistics)
	<input type="checkbox"/> Trevor Murrells (Nursing, Midwifery and Palliative Care)
	<input type="checkbox"/> Gao Wei (Nursing, Midwifery and Palliative Care)
	<input type="checkbox"/> Caroline Murphy (Core KCTU Staff)
	<input type="checkbox"/> Joanna Kelly (Core KCTU Staff)
	<input type="checkbox"/> Sarah Byford (King's Health Economics)
	<input type="checkbox"/> Paul McCrone (King's Health Economics)
	<input type="checkbox"/> Barbara Barrett (King's Health Economics)
	<input type="checkbox"/> Renee Romeo (King's Health Economics)
	<input type="checkbox"/> James Shearer (King's Health Economics)
	<input type="checkbox"/> Mark Pennington (King's Health Economics)
	<input type="checkbox"/> Julia Fox-Rushby (King's Health Economics)
	<input type="checkbox"/> Vanessa Lawrence (Qualitative Social Scientist)
	<input type="checkbox"/> Angela Cape (GSTT adult trials pharmacist)
	<input type="checkbox"/> Glynis Ivin (SLaM Pharmacist)
<input type="checkbox"/> Stuart Chandler (KCH Pharmacist)	
<input type="checkbox"/> Annette Briley (Women's Health)	
Other	<i>Please specify:</i>

<p>Q26. For non-KCL lead applicants/Chief Investigators, please provide names of any other KCL co-applicants*, if any:</p> <p><small>*required to co-ordinate KCL costs</small></p>	
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Q27. Do you require randomisation service	<input type="checkbox"/> NO	<i>Do not proceed</i>
	<input type="checkbox"/> YES	Go to Q28
Q28. Do you know the sample size	<input type="checkbox"/> NO	<i>Do not proceed</i>
	<input type="checkbox"/> YES	http://www.ctu.co.uk/randomisation/ please read leaflet and Complete the Q29/Q30
Q29. Please choose service level	Choose an item.	
Q30. Please provide a study sample size		
Q31. Do you require eCRF/database	<input type="checkbox"/> NO	<i>Do not proceed</i>
	<input type="checkbox"/> YES	http://www.ctu.co.uk/ecrf-database/ Please read leaflet and Complete questions below
Q32. Number of study sites		
Q33. Number of unique variables*		
	<i>*see supportive info below</i>	
Q34. Number of study years*		
	<i>*from first patient in to database lock</i>	
Q35. Number of databases*		
	<i>*see supportive info below</i>	
Q36. Expected number of data extract requests required*		
	<i>*see supportive info below</i>	

Supportive information:

Q33

Often people don't know at this stage how many unique variables will need to be programmed. Most trials collect about 500 variables so unless you plan a very large dataset, it's usually safe to assume 500 for cost estimates.

Q35

Is a secondary/therapy database needed?

A main database is used for baseline and outcome data. Some studies keep outcome assessors 'blind' to treatment allocation so they have a 'therapy database' as well - where adherence with intervention is recorded and if you will have lots of therapists, some studies also have a 'therapist' database to

record therapist characteristics. There is a small charge for splitting the dataset up into 2,3 or occasionally 4 separate databases to achieve that (the 4th is often for cluster trials, where you need to record characteristics of the 'cluster') so we just need to know whether to include these extra costs in your study.

Q36

Most trials export data every 6 months for DMC reports, but occasionally trials want an export monthly if there is a dedicated data manager running regular data checks. Mostly data checks are done via the search function and exports are not needed so often, with the exports for DMC's being used for periodic systematic checks. It depends on whether you will have resource in terms of manpower to do that work more often.