Support request instructions:

If you want to discuss an advanced or novel study design, please schedule an appointment with the Innovative Trials Hub https://ctu.co.uk/innovative-trials-hub/

If your study is in the area of mental health or neurosciences, please make an initial appointment to speak to an NIHR RSS advisor at www.ctu.co.uk/NIHR-RSS

For all other clinical areas please complete the below. Once completed, return to *ctu@kcl.ac.uk* and attach a PICOT Summary or summary of your study proposal
(Please see *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3430448/*)

Q1. Main point of Contact:

Name:

Q2. Contact details

Telephone: Email Address:

Q3. Full study title

Study title:

Q4. Study acronym

Study acronym:

Q5. Which of the following describe the planned study design, if known? (tick all that apply)

☐ Adaptive allocation	☐ Justice system based
☐ Adaptive design	☐ Medical device
☐ Basket	☐ Multi-arm, multi-stage
☐ Bayesian	☐ N-of-1
☐ Bioavailability	☐ Non-inferiority
☐ Biomarker enrichment	☐ Observational
☐ Biomarker stratified	☐ Open label
☐ Blinded	☐ Paediatric study
☐ Care home based	☐ Parallel group
☐ Clinical Investigation of a medical device	☐ Pharmacokinetic/pharmacodynamic
☐ Cluster randomised	☐ PhD Student Project (i.e., student is analysing the study as part of PhD)
☐ Combination therapy study	☐ Platform
☐ Community based	☐ Pragmatic
☐ Composite endpoint	☐ Preference
☐ Crossover	☐ Primary care based
☐ CTIMP (Clinical trial of an investigational medicinal product)	☐ Public health
☐ Decentralised	☐ Real world evaluation
☐ Definitive effectiveness	☐ Safety and tolerability
☐ Definitive efficacy	☐ Secondary care based
☐ Dose-finding	☐ Sequential Multiple Assignment Randomized Trial (SMART)
☐ Dose-escalation	☐ School based
☐ Dose-optimisation	☐ Social care
☐ Dose-ranging	☐ Superiority
☐ Drug-drug interaction	☐ Surgical
☐ Early phase safety / tolerability	☐ Stepped wedge
☐ Equivalence	☐ UK recruitment into an EU sponsored study
☐ Emergency care	☐ UK recruitment into a study sponsored beyond Europe
☐ Factorial	☐ Umbrella
☐ Feasibility	☐ Within-person design (Split-Body)
☐ First-in-human	☐ Withdrawal design
☐ International	

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Q6. Funder

☐ NIHR HTA; ☐ NIHR EME; ☐ NHR PHR; ☐ NIHR PDG; ☐ NIHR PGfAR; ☐ NIHR HSDR; ☐NIHR RfPB;
☐ NIHR i4i; ☐ NIHR RPSC; ☐ NIHR PRP ☐ Doctoral Fellowship; ☐ Postdoctoral fellowship; ☐ MRC; ☐ Industry;
☐ Wellcome Trust; ☐ European Union ☐ Charity ☐ Other, *please specify:* _____

Q7. Funding call URL

URL:

Q8. Which of the following best describes the project's current funding status? *(tick only one)*

☐ At one-stage application process
☐ At outline application stage (stage one)
☐ At full application stage (stage two)
☐ Already funded, in setup stage

Q9. Submission deadline:

Submission Date: __/__/____

Q10. What is the grant duration?

Start Date: __/__/____ End Date: __/__/____

Q11. Planned start date of patient recruitment?

Planned start date of patient recruitment: __/__/____

Q12. Services being requested from the KCTU:

☐ Web based randomisation service; ☐ Operational Support; ☐ Trial statistician; ☐ Qualitative Social Scientist;
☐ Web based study database/EDC system/ePRO/eConsent; ☐ Health Economist; ☐ Pharmacy IMP management support; ☐ Medical Device management support; ☐ Laboratory services

Q13. Will patient recruitment be: *(tick only one)*

☐UK Single Site ☐UK Multicentre ☐Multinational *(European sites only)* ☐Multinational *(with non-European Sites)*

Q14. Details of Chief Investigator / lead applicant (provide both if different)

Chief Investigator (CI)

Name:
Telephone: Email Address:

Lead Applicant (if different to CI)

Name:
Telephone: Email Address:

Q15. Substantive employer of the Chief Investigator *(tick only one)*

☐ KCL – *go to question 17*
☐ SLaM – *go to question 16*
☐ KCH – *go to question 16*
☐ GSTT – *go to question 16*
☐ Other, *please specify*_____ *& go to question 17*

Q16. If KCH, GSTT or SLaM, does the CI have an adjunct position at KCL?

☐ Yes – *please provide authorised appointment letter* ☐ No
(https://emckclac.sharepoint.com/sites/intranet-help-hr/SitePages/Adjunct-academic-appointments.aspx?web=1)

Q17. Name of the host organisation for the award:

Q18. Please provide names of any KCL academics who have already agreed to be co-applicants on the grant:

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