**Cambridge Clinical Trials Unit**

**Collaboration Request**

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| **Study Title:** |  |
| **Chief Investigator:** |  |
| **Point of Contact for the Study:** |  |
| **Position:** |  |
| **Organisation:** |  |
| **Email:** |  |
| **Telephone:** |  |

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| **1. Brief summary of research question and relevant background information (including patient or subject population/frequency of condition/problem)** |
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| **2. Aims and objectives of study** |
| What are the principal research questions to be answered? |
| **3. Why is this trial needed now?** |
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| **4. Brief summary of importance/relevance to NHS priorities and/or potential benefit to NHS or patients, and whether there are any resource or policy implications, for example an expensive new therapy or a more efficient way of treating current patients (N/A if not applicable)** |
| This is important for *Research for Patient Benefit* application |
| **5. Are you planning a pilot or feasibility study: YES/NO** |
| Explain how this will lead to the main study |
| **6. Have you performed a literature Review? YES/NO** |
| Please provide a maximum of 5 key references (ideally as pdfs) for the proposed area of research: |
| **7. Please describe your project in terms of PICOS (Patient, Intervention, Control, Outcomes and Study/Statistical design)** |
| **P - Patient Group:** |
| **I - Intervention(s):** describe all treatments and/or medications to be given |
| **C - Control:** what is the comparator treatment/medicine or placebo |
| **O - Outcomes and follow up period:** |
| **S - Study/Statistical design (e.g. pilot study, open label, randomised controlled trial, case control study, cross-over, other):** |
| **8. Is Patient and Public Involvement planned? YES/NO** |
| If yes, describe level of patient and public involvement |
| **9. Participating sites** |
| State number of anticipated participating sites and give their details:  UK sites:  EU sites:  International sites:  How many and which of above sites have confirmed willingness to participate? |
| **10. Sample size (if already performed or estimated):** |
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| **11. Estimated Recruitment Rate and total recruitment period** |
| What is this based on?  Any recruitment and retention strategies? |
| **12. Any competing studies that may affect recruitment? YES/NO** |
| If yes, provide details |
| **13. Duration of study for each participant** |
| Total treatment time:  Total Follow up time: |
| **14. Estimated date for start of study** |
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| **15. For study development and sample size calculations, you will need to provide:**   * **An estimate of your primary study outcome measure for the control group (for example response rate expected without the new intervention)** * **Also think about a clinically significant difference you would want to observe between groups for the study to be convincing (e.g. be worthwhile for funders and patients, change practise)** |
| Please provide sources/justification for these estimates from pilot work/literature: |
| **16. What are the key areas of uncertainty of this study (e.g. SD of primary endpoint, recruitment rates, true treatment effect size, dose)** |
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| **17. Is any translational research being planned? YES/NO** |
| If yes, give further details of samples and procedures |
| **18. Details and status of Interventions (IMP, placebo and medical device etc)** |
| Marketing authorisation, dosage, over encapsulation/manufacturing requirements, CE marking  status etc |
| **19. Protocol status** |
| None Outline Full Attached  Consort diagram attached |
| **20. Funding plans and status (repeat as necessary if more than 1 funder per study):** |
| Funding status:    Name of proposed funder:  Deadline for submission of funding application:  Type of application (Outline or Full):  Expected date of application outcome:  Estimated grant total (if known): |
| **21. Other Sources of Support (Drug supply, Equipment provision, Commercial support etc)** |
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| **22. Proposed Sponsorship for the research:** |
| Consider substantive employer of Chief Investigator |
| **23. Have you engaged with a Research Design Service (RDS)? YES/NO** |
| If yes, name of RDS: |
| **24. Have you approached any other CTUs regarding this study? YES/NO** |
| If yes, what was the outcome? |
| **25. Briefly describe the clinical trials experience of the Chief Investigator and the current trial team (including collaborators)** |
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| **26. CCTU collaboration required (please tick all that are required)**  **NOTE: CCTU can only act as your official Clinical Trials Unit provided it has oversight of the main trial activities** |
| |  |  | | --- | --- | | Protocol development |  | | Study/trial design |  | | Statistical design |  | | Statistical analysis |  | | Interim statistical reports for DMC |  | | Health Economics |  | | Study Coordination (to include study and participating site set-up, preparation of all essential study documents, regulatory and ethics submissions, preparation of annual reports etc) |  | | Study monitoring (mandatory for CTIMPS) |  | | Randomisation |  | | Pharmacovigilance |  | | Study specific procedures development |  | | Some IMP management (including sourcing and re-ordering) |  | | CRF design |  | | Database build and maintenance, remote data capture |  | | Data management (including data cleaning processes) |  | | Regulatory Oversight (mandatory for CTIMPs) |  | | Management of TSC/DMC |  | | Specimen/tissue management |  | | Access to other methodologist, please specify |  | | Other, please specify |  | |
| **27. Internal resources/sources of support (e.g. existing staff or funding)** |
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| **For CCTU use only** |
| CCTU Reference: |
| Date of meeting: |
| Meeting attended by: |
| Outcome of meeting and timelines |
| Comments/Further details: |
| Form completed by: |