**FIRST CONTACT QUESTIONNAIRE (FCQ)**

The form should be completed when:

1. Requesting UCL Sponsorship for Clinical Trials of Investigational Medicinal Products (CTIMP)
2. Requesting that UCL act as legal representative for a CTIMP where the Sponsor is based outside the UK/EEA.

This form is only to be used for CTIMPs as defined by the MHRA’s algorithm given here:

[*https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\_data/file/317952/Algothrim.pdf*](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/317952/Algothrim.pdf)

The Chief Investigator (CI) or delegate should complete this questionnaire as accurately as possible. The CI should be aware of and agree to the information provided.

The details provided in this questionnaire will be used to identify any risks involved in the conduct of the newly proposed clinical trial and to ensure that adequate plans are in place to manage and reduce these risks before sponsorship can be agreed and the project be indemnified by UCL.

Please contact the JRO CTIMPs team if you have any questions: [**CTIMPS@ucl.ac.uk**](mailto:CTIMPS@ucl.ac.uk)

For questions that require a ‘Yes’ or ‘No’ answer, please indicate the correct answer(s) by ticking the applicable box(es).

|  |  |
| --- | --- |
| **Full Title of Proposed Trial:** |  |
| **Short Title:** |  |
| ***1.0: Administrative Information*** | |
| **1.1 Person completing this Questionnaire:** |  |
| **1.2 Date of completion:** |  |
| **1.3 Proposed Chief Investigator (CI):** |  |
| **1.4 CI Employer Organisation:** | Substantive:  Honorary: |
| **1.5 CI Address:** |  |
| **1.6 CI Email:** |  |
| **1.7 CI Telephone:** |  |
| **1.8 Name of CI’s Head of department at UCL** |  |
| **1.9 Indicate which of the following is requested:** | UCL Sponsorship of a Clinical Trial  UCL to act as Legal Representative for a Sponsor outside the UK/EU |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ***2.0: Funding / Costing*** *Please note that for all trials requesting UCL sponsorship, full economic costing of the trial is required to be signed off by JRO finance.* | | | | | | | |
|
| **2.1 Departmental Administrator:**  *(i.e. person responsible for assistance with completion of Worktribe at your UCL department/Institute)* | | | **Name:**  **Department:**  **Tel:**  **Email:** | |  | | |
| **2.2 Department Head of Finance:** | | | | |  | | |
| **2.3 Has the trial already been costed?**  *If yes, include costing on submission of this questionnaire.* | | | | | | Yes No | |
| **2.4 Has funding already been secured for the trial?**  *If yes, please provide the details of funding received.*  *(i.e. copy of award letter(s) and a breakdown of funding provided)* | | | | | | Yes No | |
| **2.5 Worktribe Number for trial:** | | | | | | | |
| **2.6 How is the trial being funded?** | | *(Check more than one box if multiple sources of funding apply)*  Commercial source  Public or charity funded  In-house funds, specify the account details below: | | | | | |
| **2.7 Funder (s):** | | | | **Status:** | | | **Funding application deadline:** |
| **1.** |  | | | Confirmed Anticipated | | |  |
| **2.** |  | | | Confirmed Anticipated | | |  |
| **3.** |  | | | Confirmed Anticipated | | |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| ***3.0: Chief Investigator (CI) Experience*** | | | | | | |
| **3.1 Has the CI ever attended a GCP training course?** | | | | Yes No  *If yes, date*: | | |
| **3.2 Number of CTIMPs CI has been named…** | | | | | | |
| **Principal Investigator for:** | Commercial trials: |  | | | | |
| Non-Commercial trials: |  | | | | |
| **Chief Investigator for:** | Commercial trials: |  | | | | |
| Non-Commercial trials: | Single centre: | | |  | |
| Multi centre: | | |  | Number of centres (largest): |
| **3.3 Has the Chief Investigator been involved in a clinical trial of the same phase as the proposed one?** | | | Yes No  *If yes, detail involvement in trial e.g., CI or PI*: | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| ***4.0: CI’s Experience of Investigational Medicinal Product (IMP) and Trial Procedures*** | | | |
| **4.1 Complete below table for all study IMP(s):** | | | |
| **IMP Name** | | **CI’s experience of use of IMP** *(where use implies handling, administration and familiarity with IMP safety profile)* | |
| **1.** |  | No experience Limited experience (<50 patients)  Experienced (>50 patients) | |
| **2.** |  | No experience Limited experience (<50 patients)  Experienced (>50 patients) | |
| **3.** |  | No experience Limited experience (<50 patients)  Experienced (>50 patients) | |
| **4.** |  | No experience Limited experience (<50 patients)  Experienced (>50 patients) | |
| **4.2 Additional information / comments** regarding experience or risk related to IMP, *if required*: | | | |
| **4.3 Complete for study interventions which are HIGH RISK / NOVEL procedures *e.g. surgical, non-CE marked device, unlicensed non-investigational products (NIMPs)*** | | | |
| **Intervention** | | **CI’s experience of intervention** | **Proposed control measure of identified risk** |
| **1.** |  | No experience  Limited experience (<50)  Experienced (>50 patients) |  |
| **2.** |  | No experience  Limited experience (<50)  Experienced (>50 patients) |  |
| **3.** |  | No experience  Limited experience (<50)  Experienced (>50 patients) |  |
| **4.4 Additional information / comments regarding experience or risk related to trial interventions**, *if required*: | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***Section 5.0: Trial Size and Sites*** | | | | |
| **5.1 Total anticipated number of participants:** | | | |  |
| **5.2 Estimated recruitment period for *all participants*:** *(months/years)* | | | |  |
| **5.3 Total duration of the trial:** | | | |  |
| Treatment duration *per participant* (e.g. single administration, or administrations over X number days/weeks/months): | | | |  |
| Follow-up period *per participant* (e.g. number of weeks, months, years): | | | |  |
| **5.4 Is the trial multi-site?** | Yes  No | | | |
| **5.5 Name of lead NHS site:** | |  | | |
| **5.6 Lead NHS site R&D contact details:** | |  | | |
| **5.7 Is the lead site R&D office aware of the proposed study?** | | Yes  No | | |
| **5.8 Number of sites:** | | Number of Sites in UK: |  | |
| Number of Sites in EU: |  | |
| Number of Sites non-EU: |  | |
| **5.9 Names of non-UK countries with proposed trial sites:** | |  | | |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ***Section 6.0: Trial Design and Complexity*** | | | | | | | | |
| **6.1 Proposed phase of trial:** | | |  | | | | | |
| Phase l - Human Pharmacology | | | Phase I/IIa or I/IIb- Safety and dose ranging study | | | | | |
| Phase ll - Therapeutic exploratory | | | Phase lll - Therapeutic confirmatory | | | | Phase lV - Therapeutic | |
| **6.2 Trial Design:** *(indicate all that apply)* | | | | | | | | |
| Open label | Placebo Controlled | | | Randomised – ***Indicate № of trial arms***: | | | |  |
| Blinded | Cross over | | | Other - ***specify design (e.g. 2x2 factorial):*** | | | |  |
| **6.3 Trial subjects: (***indicate all that apply)* | | | | | | | | |
| Healthy volunteers | | | | | | Children under 5 years of age | | |
| Patients | | | | | | Children between 5 -16 years of age | | |
| Patients with poor prognosis/terminal disease | | | | | | Pregnant or nursing women | | |
| Patients incapable of giving consent personally | | | | | | Women of Childbearing potential *(with no contraception requirement in protocol)* | | |
| Patients in emergency situations *(e.g., unconscious)* | | | | | |
| Other (*specify)*: | | | | | | | | |
| **6.4 Is the scope of the trial prophylactic?** | | | | | Yes  No | | | |
| **6.5 Primary Trial Objective(s):** | |  | | | | | | |
| **6.6 Secondary Trial Objective(s):** | |  | | | | | | |
| **Randomised Trials Only:** | | | | | | | | |
| **6.7 Have randomisation personnel/systems already been identified?**  No  Yes *If yes, please specify*: | | | | | | | | |
| **6.8 Is it already known who will assign the treatment allocations?**  No  Yes *If yes, please specify*: | | | | | | | | |
| **Blinded Trials Only:** *A system for 24-hour unblinding must be in place prior to initiation of the trial.*  *(UCLH pharmacies are not able to provide this service)* | | | | | | | | |
| **6.9 Have personnel/systems for unblinding during work hours already been identified?**  No  Yes *If yes, please specify*: | | | | | | | | |
| **6.10 Have personnel/systems for unblinding *outside* work hours already been identified?**  No  Yes *If yes, please specify*: | | | | | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| ***Section 7.0: Statistical Support***  *All trials sponsored by UCL require a named trial statistician to be an integral part of the trial team. Where the trial involves ONLY descriptive statistics, such as an early phase or small pilot trial, the person responsible must have completed at least a short course in statistics.* | | | |
| **7.1 Has a trial statistician been identified?** | | | Yes  No |
| **7.2 Name and institution of the trial statistician / nominated individual for descriptive stats:** |  | | |
| **7.3 Qualification of Statistical Support Person:** | | | |
| PhD in Statistics or Epidemiology | | Other *(specify)*: | |
| MSc in Statistics or Epidemiology | | Name of Short Course *(if applicable)*: | |
| BSc in Statistics | |
| **7.4 Has this statistician already given you advice about the design and analysis for this trial?** | | | Yes  No |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ***Section 8.0: Trial Management*** | | | | | | | | |
| **8.1 Is the intention to use a Clinical Research Organisation (CRO) or a Clinical Trials Unit (CTU) to support the management of this trial?** | | | | | | Yes  No | | |
| Not sure | | |
| **8.2 Name of CRO or CTU** *(if known/applicable)***:**  *JRO maintains the right to audit any organisation to whom sponsor’s duties are delegated* | |  | | | | | | |
| **8.3 Contact name and e-mail:** | |  | | | | | | |
| **8.4 Proposed duties to be assigned to CRO or CTU:** | |  | | | | | | |
| **8.5 Will any of the following staff be employed for the trial?** | | | | | | | | |
|  | | | Planned | Already in place | Not planned / required | | How is the post funded or to be funded? *Directly employed/allocated by Trust. Other (please specify)* |
| **Research Fellow** | | |  |  |  | |  |
| **Research Nurse** | | |  |  |  | |  |
| **Data Manager** | | |  |  |  | |  |
| **Clinical Trial Co-ordinator / Trial Manager**  *(required for Phase I/II, recommended for multicentre trials)* | | |  |  |  | |  |
| **Other** *(Specify below)*: | | | **☐** | **☐** |  | |  |
| **8.6 Are any of these Committees already in place/planned for the trial?** | | | | | | | | |
| *As a minimum a TMG is required.*  *The JRO stipulates that Phase I studies have an IDMC/DMC* | Trial Management Group (TMG) | | | | | Yes  No | | |
| Trial Steering Committee (TSC) | | | | | Yes  No | | |
| Independent Data Monitoring Committee (IDMC) | | | | | Yes  No | | |

|  |  |
| --- | --- |
| ***Section 9.0: Data Management*** | |
| **9.1 Will the CRF be paper, electronic or a combination?**  *If using an eCRF please specify which proposed system will be used and who will be responsible for setting this up.* |  |
| **9.2 What proposed database will be used for data entry and analysis, and who will be responsible for setting this up?** |  |
| **9.3 Who will perform data entry?** |  |
| **9.4 Where will the trial database be held?** |  |
| **9.5 Will any data be transferred outside of UCL?**  No  Yes *If yes, specify where*: | |
| **9.6 Will any data be transferred to a commercial entity or another academic institution at any point during the trial?**  No  Yes *If yes, specify where*: | |

|  |  |  |
| --- | --- | --- |
| ***Section 10.0: Laboratory Information*** | | |
| **10.1 Will you be using central labs to analyse patient samples?** | | Yes  No |
| **10.2 Have you already identified labs you would like to use?** | | Yes  No |
| **10.3 Lab name and address (***if known)* |  | |
| **10.4 Please specify if the assays will be to confirm eligibility or primary / secondary / exploratory endpoint analysis / dose stratification** |  | |
| **10.5 Please specify if all assays are CE/UKCA marked** |  | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ***Section 11.0 IMP Information***  *Please complete and repeat* ***both*** *sections 11 and 12 for each IMP including Placebo.*  *Additional blank tables are available at the end of this form.* | | | | | | | |
| **11.1 Product name:** | |  | | | | | |
|  | **Route of administration:** |  | | | *Is this as per the SmPC?* | | Yes  No  N/A |
| **Dose:** |  | | | *Is this as per the SmPC?* | | Yes  No  N/A |
| **11.2 Products with a Marketing Authorisation (MA) in UK or EEA**  *Check box if product does NOT have a marketing authorization in UK or EEA*   *and* ***go to section 11.3*** | | | | | | | |
| Any brand / generic product to be used  Specific brand to be used **Specify manufacturer**: | | | | | | | |
| **a) Is the IMP to be used within its licensed indication as per the SmPC?**  Yes  No *If no, please specify*: | | | | | | | |
| **b) Is the IMP to be used in the same patient population as per the SmPC?**  Yes  No *If no, please specify*: | | | | | | | |
| **c) Will IMP be used in its marketed form?** (i.e. no substantial modifications e.g. radiolabelling, over encapsulation)  Yes  No *If no, please specify*: | | | | | | | |
| **11.3 Name of Active substance:** | | |  | | | | |
| **11.4 Pharmaceutical Dosage Form:** | | | | Oral  Parenteral | | | |
| Other, please specify: | | | |
| **11.5 Is the IMP** | | | | | | | |
| a) Biological or Biotechnological Product | | | | | | Yes  No | |
| b) Advanced Therapy Medicinal Product | | | | | | Yes  No | |
| c) Classified as Genetically Modified Organism (GMO) | | | | | | Yes  No | |
| d) Consisting of tissues or cells | | | | | | Yes  No | |
| **11.6 How will the IMP be stored?** | | | | as per SmPC *(for licensed IMPs only)* | | | |
| Other, please specify: | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| ***Section 12.0: Source of IMP including Placebo***  *Check box if* *hospital stock to be used* (budget to be agreed by pharmacy*) and* ***go to section 13.0*** | | | |
| **12.1 Is a Pharmaceutical Company supplying the IMP for free?**  *if yes go to 12.3* | | Yes  No | |
| Company name: | | | |
| **12.2 Will the IMP be manufactured by a third-party Contract Drug Manufacturing Organisation?** | | Yes  No  Don’t know | |
| Name: | | | |
| **12.3 Will IMP be sourced from the UK?** | | Yes  No *(see 12.3.1 & 2)* | |
| **12.3.1** If no, from which country will IMP be sourced? | **12.3.2** Has an importer been identified? Yes  No  Provide details: | | |
| **12.4 Does the IMP require specific manufacturing (i.e. non-commercial stock) for this trial?**  Yes  No If known, name manufacturer:  Address:  Please detail Active Pharmaceutical Ingredient and source: | | | |
| **12.5 If answered NO to 12.1, 12.3 and 12.4 please specify where and how the IMP will be sourced for the trial:** | | | |
| **12.6 Has negotiation with the manufacturer / importer / supplier been initiated?**  If yes, provide details: | | | Yes  No  N/A |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***Section 13.0: Non Investigational Medicinal Products (NIMPs)*** | | | | | |
| **13.1 Please list all known NIMPs** *(e.g. rescue medication, background treatment)*: | | | | | |
| **NIMP** | | **Licenced/**  **Unlicenced Product** | **Proposed Dose** (including units) | **Route of Administration** | **Frequency and Total Dose** |
| **1.** |  |  |  |  |  |
| **2.** |  |  |  |  |  |
| **3.** |  |  |  |  |  |
| **4.** |  |  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***Section 14.0: IMP Supply Arrangements / Conflict of Interest:***  *Complete this section considering all commercial parties involved in the trial (e.g. IMP or Device suppliers)* | | | | |
|  | Yes | | No | N/A |
| **14.1 Is the CI being paid directly by any commercial party to participate in the trial?** |  | |  |  |
| **14.2 Do any of the commercial parties involved in the trial plan to use the trial data for purposes of licensing the drug or varying the current marketing authorisation?** |  | |  |  |
| **14.3 Does the CI occupy a position of Director, Partner, Consultant or Trustee in any of the commercial parties involved in the trial?** |  | |  |  |
| **14.4 Is the CI a member of a committee providing advice to any of the commercial parties involved in the trial?** |  | |  |  |
| **14.5 Does the CI have any significant financial interests in any of the commercial parties or products involved in the trial?** |  | |  |  |
| **14.6 Are there intellectual property issues that should be highlighted?** |  | |  |  |
| *If the answer is yes to any of the questions above (14.1-14.6) please provide details:* | | | | |
| **14.7 Will UCL Business be involved?** | | Yes  No | | |
| **14.8 Does the CI or members of his/her family have any significant financial interests in the company/manufacturer supplying the IMP or funding the trial?**  Significant financial interests are shares or share options, securities, payments for services such as consultancy or payments in respect of intellectual property. IP includes license fees, royalties and revenue sharing arrangements. **PLEASE INCLUDE ANY PAYMENTS MADE UNDER UCL ROYALTY SHARING SCHEME.**  *If yes, provide details of financial interest*: | | Yes  No | | |
| **14.9 Are you aware of any co-investigators planned to work on the trial who have a potential conflict of interest (as per 14.1-14.5 and 14.8 above)**  *If yes, provide details*: | | Yes  No | | |
| **14.10 Is the CI currently under investigation for misconduct, or for any other reason?**  *If yes, provide details:* | | Yes  No | | |
| **14.11 Are there any other issues that may impede on the decision of UCL to take on sponsorship or legal representation for the above trial?**  *If yes, provide details:* | | Yes  No | | |

|  |  |  |  |
| --- | --- | --- | --- |
| ***Section 15.0: Legal Representative Only***  N/A Sponsorship Request Only | | | |
| **15.1 Will the requesting clinician be the**  Chief Investigator OR  Principal Investigator | | | |
| **15.2 Name of Sponsor Organisation:** | |  | |
| **15.3 Primary Sponsor Contact Details:** | **Name:**  **Address:**  **Tel:**  **Email:** |  | |
| **15.4 Country in which Sponsor is based:** | |  | |
| **15.5 Does the Sponsor require UCL to act Legal Representative only in name *(i.e. without taking on any Sponsor responsibilities)*?** | | | Yes  No |
| **15.6 If answered no above *(15.5)*, please provide details of services the Sponsor would like UCL to provide / responsibilities the Sponsor would like UCL to take on *(if known)*:** | | | |

Thank you for completing this questionnaire. Please email the form to the JRO CTIMPs team member who issued the questionnaire, together with

1) Costing for the trial (if already completed)

2) Copies of all funding award letters (if some/all funds secured)

**Table for additional IMPs including Placebo.**

This is a repeat table which must be copied and completed for each further IMP.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ***Section 11.0 IMP Information*** *(Additional table)* | | | | | | | |
| **11.1 Product name:** | |  | | | | | |
|  | **Route of administration:** |  | | | *Is this as per the SmPC?* | | Yes  No  N/A |
| **Dose:** |  | | | *Is this as per the SmPC?* | | Yes  No N/A |
| **11.2 Products with a Marketing Authorisation (MA) in UK or EEA**  *Check box if product does NOT have a marketing authorization in UK or EEA*   *and* ***go to section 11.3*** | | | | | | | |
| Any brand / generic product to be used  Specific brand to be used **Specify manufacturer**: | | | | | | | |
| **a) Is the IMP to be used within its licensed indication as per the SmPC?**  Yes  No *If no, please specify*: | | | | | | | |
| **b) Is the IMP to be used in the same patient population as per the SmPC?**  Yes  No *If no, please specify*: | | | | | | | |
| **c) Will IMP be used in its marketed form?** (i.e. no substantial modifications e.g. radiolabelling, over encapsulation)  Yes  No *If no, please specify*: | | | | | | | |
| **11.3 Name of Active substance:** | | |  | | | | |
| **11.4 Pharmaceutical Dosage Form:** | | | | Oral  Parenteral | | | |
| Other – *specify*: | | | |
| **11.5 Is the IMP** | | | | | | | |
| a) Biological or Biotechnological Product | | | | | | Yes  No | |
| b) Advanced Therapy Medicinal Product | | | | | | Yes  No | |
| c) Classified as Genetically Modified Organism (GMO) | | | | | | Yes  No | |
| d) Consisting of tissues or cells | | | | | | Yes  No | |
| **11.6 How will the IMP be stored?** | | | | as per SmPC *(for licensed IMPs only)* | | | |
| Other, *please specify*: | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| ***Section 12.0: Source of IMP including Placebo*** *(Additional table)* | | | |
| **12.1 Is a Pharmaceutical Company supplying the IMP for free?**  *if yes go to 12.3* | | Yes  No | |
| Company name: | | | |
| **12.2 Will the IMP be manufactured by a third party Contract Drug Manufacturing Organisation?** | | Yes  No  Don’t know | |
| Name: | | | |
| **12.3 Will IMP be sourced from the UK?** | | Yes  No *(see 12.3.1 & 2)* | |
| **12.3.1** If no, from which country will IMP be sourced? | **12.3.2** Has an importer been identified? Yes  No  Provide details: | | |
| **12.4 Does the IMP require specific manufacturing (i.e. non-commercial stock) for this trial?**  **Yes  No If known, name manufacturer:**  **Address:**  **Please detail Active Pharmaceutical Ingredient and source:** | | | |
| **12.5 If answered NO to 12.1, 12.3 and 12.4 please specify where and how the IMP will be sourced for the trial:** | | | |
| **12.6 Has negotiation with the manufacturer / importer / supplier been initiated?**  If yes, provide details: | | | Yes  No  N/A |