

**UCL FIRST CONTACT QUESTIONNAIRE(FCQ)**

The Chief Investigator (CI) or delegate should complete this questionnaire as accurately as possible. The form should be completed when:

1. Requesting UCL Sponsorship for a 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 EU.

The CI should be aware of and agree the information provided.

This form is only to be used for CTIMPs as defined by the MHRA’s algorithm given here: <http://www.mhra.gov.uk/home/groups/lunit1/documents/websiteresources/con009394.pdf>

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).**

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| **Title of Proposed Trial:** |  |
| **Short Title:** |  |
| ***1.0: Administrative Information*** | |
| **1.1 Person completing this Questionnaire:** |  |
| **1.2 Chief Investigator (CI):** |  |
| **1.3 CI Employer:** | (include substantive and honorary appointments) |
| **1.4 Address:** |  |
| **1.5 Email:** |  |
| **1.6 Telephone:** |  |
| **1.7 Indicate which of the following is requested:** | **UCL Sponsorship of a Clinical Trial**  **UCL to act as EU Legal Representative for a Sponsor outside the EU** |

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| ***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.* | | | | |
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| **2.1 Departmental Administrator:**  *(i.e. person responsible form completion of local pFACT)* | | **Name:**  **Department:**  **Tel:**  **Email:** | | |
| **2.2 Has the trial already been costed?** Yes No  If yes, include costing on submission of this questionnaire. | | | | |
| **2.3 Has funding already been secured for the trial?** Yes No  *If yes, please provide the details of funding received (i.e. copy of any award letter(s) and a breakdown of funding provided)* | | | | |
| **2.4 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: | | | |
| **2.5 Funder (s):** | | | **Status:** | **Funding application deadline:** | |
| 1. | | | Confirmed Anticipated |  | |
| 2. | | | Confirmed Anticipated |  | |
| 3. | | | Confirmed Anticipated |  | |

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| ***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 named CI has been:** | | | | |
| Principle Investigator? | Commercial: | | | |
| Non-Commercial: | | | |
| Chief Investigator? | Commercial: | | | |
| Non-Commercial | 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 | | | | |

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| ***4.0: CI’s Experience of IMPs and Trial Procedures***  ***4.1 Complete table for all study IMP(s):*** | | | | |
| **Name IMP** | | | **CI’s experience of use of IMP** *(where use implies handling, administration and familiarity with IMP safety profile)* | | |
| **1.** |  | | No experience Limited experience (<50)  Experienced (>50) | | |
| **2.** |  | | No experience Limited experience (<50)  Experienced (>50) | | |
| **3.** |  | | No experience Limited experience (<50)  Experienced (>50) | | |
| **4.** |  | | No experience Limited experience (<50)  Experienced (>50) | | |
| **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 NIMPs** | | | | |
| **Name intervention** | | **CI’s experience of intervention** | | **Proposed control measure of identified risk** | |
| **1.** |  | No experience  Limited experience (<50)  Experienced (>50) | |  | |
| **2.** |  | No experience  Limited experience (<50)  Experienced (>50) | |  | |
| **3.** |  | No experience  Limited experience (<50)  Experienced (>50) | |  | |
| **4.** |  | No experience  Limited experience (<50)  Experienced (>50) | |  | |
| **4.4 Additional information**/comments regarding experience or risk related to trial interventions, if required: | | | | |

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

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| ***Section 6.0: Trial Design and Complexity*** | |
| **6.1 Phase of trial:**  Phase l - Human Pharmacology Phase I/IIa - 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  Patients  Patients with poor prognosis/terminal disease  Patients incapable of giving consent personally Patients in emergency situations (e.g. unconscious)  Children under 5 years of age  Children between 5 -16 years of age  Pregnant or nursing women  Women of Child bearing potential (no contraception  Other – specify: requirement in protocol) | |
| **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: | |

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| ***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 \*delete as appropriate :** |  | |
| Qualification  PhD in Statistics or Epidemiology  MSc in Statistics or Epidemiology  BSc in Statistics  Other (specify):  Name of Short Course (if applicable): | | |
| **7.3 Has this statistician already given you advice about the design and analysis for this trial?** | | Yes  No |

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| ***Section 8.0: Trial and Data 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 CRO or CTU** (if known)**:**  *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 How will the trial data be managed?**  (E.g. eCRF/paper CRF, who performs data entry, identifies database/software for data entry and analysis, etc.) | |  | | | | | |
| **8.6 Where will the trial data be held?** | |  | | | | | |
| **8.7 Will any data be transferred outside of UCL?** | |  | | | | | |
| **8.8 Will any of the following staff be employed for the trial?** | | | | | | | |
|  | | | Planned | Already in place | | Not planned/ required | | |
| Research Fellow | | |  |  | |  | | |
| Research Nurse | | |  |  | |  | | |
| Data Manager | | |  |  | |  | | |
| Clinical Trial Co-ordinator /Trial Manager  (required for Phase I/II, recommended for multicentre trials) | | |  |  | |  | | |
| Monitor  (required for phase I and I/II trials, JRO will advise) | | |  |  | |  | | |
| Other (Please specify): | | |  |  | |  | | |
| **8.9 Are any of these Committees already in place/planned for the trial?** | | | | | | | | |
| As a minimum a TMG is required, and the JRO recommend that Phase I studies have an IDMC | Trial Management Group (TMG) | | | | | | Yes  No |
| Trial Steering Committee (TSC) | | | | | | Yes  No |
| Independent Data Monitoring Committee (IDMC) | | | | | | Yes  No |

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| ***Section 9.0 IMP Information*** *(Please complete and repeat* ***both*** *sections 9 and 10 for each IMP including Placebo). Additional blank tables available at the end of this form.* | | | |
| **9.1 Product name:** | |  | |
| **Dose: is this as per the SmPc?**  Yes  No  n/a  **Route of administration: is this as per the SmPc?**  Yes  No  n/a | | | |
| **9.2 Products with a Marketing Authorisation in UK or EEA**  *Check box if product does NOT have a marketing authorization in UK or EEA*   *go to section* 9.3 | | | |
| 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 further manufacturing required e.g. radiolabelling, over encapsulation)  Yes  No If no, please specify: | | | |
| **9.3 Name of Active substance:** |  | | |
| **9.4 Pharmaceutical Form:** | Tablet / Capsule  Powder for reconstitution  Other – specify: | | |
| **9.5 Is the IMP** | | | |
| a) Biological or Biotechnological Product | | | Yes  No | |
| b) Advanced Therapy Medicinal Product | | | Yes  No | |
| c) IMP classified as Genetically Modified Organism (GMO) | | | Yes  No | |
| d) IMP consisting of tissues or cells | | | Yes  No | |
| **9.6 How will the IMP be stored?**  as per SmPC Other, please specify: | | | |

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| ***Section 10.0: Source of IMP including Placebo***  *n/a (hospital stock to be used* budget to be agreed by pharmacy/PCT*) go to section 11.0* |
| **10.1 Is a Pharmaceutical Company supplying the IMP for free?**   No  Yes  Company name: |
| **10.2 Will the IMP be sourced from a wholesaler?**  No  Yes  Don’t know  Name: |
| **10.3 Does the IMP have an MA in the UK?**  No  Yes  NA (Placebo)  If no, in which country is the IMP licensed? |
| **10.4 Will IMP be sourced in the UK?**   Yes  No (see 10.4.1 &2) |
| **10.4.1 If ‘No’, where will IMP be sourced?** Country:  **10.4.2 Has an importer been identified?**  No  Yes provide details: |
| **10.5 Does the IMP require specific manufacturing (i.e. not available to purchase) for this trial?**  No  Yes If known, name manufacturer:  Please detail Active Pharmaceutical Ingredient and source: |
| **10.6 If answered NO to 10.1,10.2,10.3 and 10.5 please specify where and how the IMP will be sourced for the trial:** |
| **10.7 Has negotiation with the manufacturer/ importer/ supplier been initiated?**  Yes  No  NA |

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| ***Section 11.0: Non Investigational Medicinal Products (NIMPs)*** | | | | |
| **11.1 Please list all known NIMPs** (Non Investigational Medicinal Products, such as rescue medication, background treatment): | | | | |
| **NIMP** | | **Proposed Dose**  (including units) | **Route of administration** | **Frequency & Total Duration** |
| **1.** |  |  |  |  |
| **2.** |  |  |  |  |
| **3.** |  |  |  |  |
| **4.** |  |  |  |  |

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| ***Section 12.0: 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 |
| **12.1 Is the CI being paid directly by any commercial party to participate in the trial?** |  | |  |  |
| **12.2 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?** |  | |  |  |
| **12.3 Does the CI occupy a position of Director, Partner, Consultant or Trustee in any of the commercial parties involved in the trial?** |  | |  |  |
| **12.4 Is the CI a member of a committee providing advice to any of the commercial parties involved in the trial?** |  | |  |  |
| **12.5 Does the CI have any significant financial interests in any of the commercial parties involved in the trial?** |  | |  |  |
| **12.6 Are there intellectual property issues that should be highlighted?** |  | |  |  |
| ***12.6.1 If the answer is yes to any of the questions above (11.1-11.7) please provide details:*** | | | | |
| **12.7 Will UCL Business be involved?** | | Yes  No | | |
| **12.8 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.** | | Yes  No | | |
| ***12.8.1******Details of Financial Interest:*** | | | | |
| **12.9 Is the CI currently under investigation for misconduct, or for any other reason?** | | Yes  No | | |
| **12.10 Are there any other issues that may impede on the decision of UCL to take on sponsorship/ EU representation for the above trial?** | | Yes  No | | |
| ***12.10.1 If yes please detail:*** | | | | |

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| ***Section 13.0: EU Legal Representative Only***  N/A Sponsorship Request Only | | |
| **13.1 Will the requesting clinician be the**  Chief Investigator OR  Principal Investigator | | |
| **13.2 Name of Sponsor Organisation** |  | |
| **13.3 Primary Sponsor Contact Details** | Name:  Address:  Tel:  Email: | |
| **13.4 Country in which Sponsor is based** |  | |
| **13.5 Does the Sponsor require UCL to act Legal Representative only in name (i.e. without taking on any Sponsor responsibilities)?** | | Yes  No |
| **13.6 If answered no above (13.5), 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. On completion, 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)

For additional IMPs (including Placebo) please go to next page **Table for additional IMPs including Placebo.** This is a repeat table which must be copied and completed for each further IMP.

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| ***Section 14.0 IMP Information*** *(Please complete and repeat* ***both*** *sections 9 and 10 for each IMP including Placebo). Additional blank tables available at the end of this form.* | | | |
| **14.1 Product name:** | |  | |
| **Dose: is this as per the SmPc?**  Yes  No  n/a  **Route of administration: is this as per the SmPc?**  Yes  No  n/a | | | |
| **14.2 Products with a Marketing Authorisation in UK or EEA**  *Check box if product does NOT have a marketing authorization in UK or EEA*   *go to section* 14.3 | | | |
| 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 further manufacturing required e.g. radiolabelling, over encapsulation)  Yes  No If no, please specify: | | | |
| **14.3 Name of Active substance:** |  | | |
| **14.4 Pharmaceutical Form:** | Tablet / Capsule  Powder for reconstitution  Other – specify: | | |
| **14.5 Is the IMP** | | | |
| a) Biological or Biotechnological Product | | | Yes  No | |
| b) Advanced Therapy Medicinal Product | | | Yes  No | |
| c) IMP classified as Genetically Modified Organism (GMO) | | | Yes  No | |
| d) IMP consisting of tissues or cells | | | Yes  No | |
| **14.6 How will the IMP be stored?**  as per SmPC Other, please specify: | | | |

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| ***Section 15.0: Source of IMP including Placebo***  *n/a (hospital stock to be used* budget to be agreed by pharmacy/PCT*)* |
| **15.1 Is a Pharmaceutical Company supplying the IMP for free?**   No  Yes  Company name: |
| **15.2 Will the IMP be sourced from a wholesaler?**  No  Yes  Don’t know  Name: |
| **15.3 Does the IMP have an MA in the UK?**  No  Yes  NA (Placebo)  If no, in which country is the IMP licensed?: |
| **15.4 Will IMP be sourced in the UK?**   Yes  No (see 15.4.1 &2) |
| **15.4.1 If ‘No’, where will IMP be sourced?** Country:  **15.4.2 Has an importer been identified?**  No  Yes provide details: |
| **15.5 Does the IMP require specific manufacturing (i.e. not available to purchase) for this trial?**  No  Yes If known, name manufacturer:  Please detail Active Pharmaceutical Ingredient and source: |
| **15.6 If answered NO to 15.1,15.2,15.3 and 15.5 please specify where and how the IMP will be sourced for the trial:** |
| **15.7 Has negotiation with the manufacturer/ importer/ supplier been initiated?**  Yes  No  NA |