**Managing Organisation Suitability Questionnaire**

***[Add extra trial specific questions if needed to end of question list – remove red text prior to sending]***

Please complete this questionnaire and return it to the JRO Sponsor Regulatory Advisor / Regulatory Manager - ATMP at your earliest convenience.

**Sponsor ID**:

**Title of study**:

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| --- | --- | --- |
| **Contact Details** | | |
| **Main contact person** | Name: |  |
| Address: |  |
| Contact number: |  |
| Email: |  |
| **Alternative contact person** | Name: |  |
| Address: |  |
| Contact Number: |  |
| Email: |  |
| **Person responsible for clinical trials agreements** | Name: |  |
| Address: |  |
| Contact number: |  |
| Email: |  |

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| **Managing Organisation suitability questions** | | | | | |
| 1. Do you have accredited CTU status? | Yes  No | | If yes please provide certificate: | | |
| 1. How many clinical trials with a similar level of complexity have you managed to date *(similar number of sites, patients and trial arms*)? |  | | | | |
| 1. Have you managed any trials in this therapeutic area/disease area? | Yes  No | | | | |
| 1. What is your experience of managing international CTIMPs *(if applicable)* |  | | | | |
| 1. How many trials will be ongoing or in follow-up when this study is initiated? | Ongoing: | | | | Follow-up: |
| 1. How often are staff required to attend GCP training, and how do you ensure all staff are adequately trained to work on the trials? |  | | | | |
| 1. Are staff experienced in phase I clinical trials *(if applicable)* | Yes No | | | If yes, please specify: | |
| N/A | | |
| 1. How will this trial be managed within the CTU, and what staff roles will be costed into a grant to ensure management of the trial? |  | | | | |
| 1. Do you have SOPs and systems in place for safety-reportingon CTIMP trialswhich are in compliance with GCP guidelines and all applicable UK and international regulations? | Yes  No | | | | |
| 1. Do you require access to UCL Eudravigilance or eSUSAR? | Yes  No | If yes, please specify: | | | |
| 1. Are you able to provide data management, and if so what type of database will be used? | Yes  No | If yes, please specify: | | | |
| 1. If you are providing data management, will you be able to provide the data management plan and evidence of the validation of your database to the sponsor? | Yes  No | | | | |
| 1. Will you be able to provide a data flow of trial data as per GDPR? | Yes  No | | | | |
| 1. Are you able to provide monitoring services that are in compliance with GCP guidelines and all applicable international / local regulations? | Yes  No | If yes, please specify the type of monitoring you would perform for the proposed trial: | | | |
| 1. Do you have systems in place to provide monitoring reports to the sponsor? | Yes  No | | | | |
| 1. Do you have an established Quality Management system that complies with the GCP guidelines and all applicable international / local regulations? | Yes  No | | | | |
| 1. Do you provide a 24 hour unblinding service? | Yes  No | | | | |
| 1. Are you able to provide a list of your SOPs and supply those requested by the sponsor for review? | Yes  No | | | | |
| 1. Will you be implementing an electronic or paper TMF for this trial? | Paper  eTMF | | | | |
| 1. Can you provide your standard TMF structure for review? | Yes  No | | | | |
| 1. Are you able to complete the End of Study Results Report on the trial registry? | Yes  No | | | | |
| 1. How will you transfer the study data to the Sponsor at the end of trial? |  | | | | |
| 1. Can you provide a summary of your most recent audit? | Yes  No | | | | |
| 1. Are you happy for UCL to undertake a systems audit prior to selection? | Yes  No | | | | |
| 1. Have you gone through a GCP MHRA inspection? | Yes  No | | | | |
| 1. Have you reported “urgent safety measures” or serious breaches to the MHRA /sponsor in the past? | Yes  No | | | | |
| 1. [Add additional trial specific questions as needed, *or delete this row*] |  | | | | |

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| **Completed by:** | | | | | |
| **Name:** |  | **Position:** |  | **Date:** |  |

Please do not hesitate to contact us should you require any further information about the trial.

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| ***JRO Use Only*** | | | | |
| ***Reviewed by:*** | | | | |
| ***Name:*** |  | | ***Position:*** |  |
| ***Comments:*** | | | | |
| ***Actions/Escalation Required:*** | | | | |
| ***Responses to Actions/Escalations Required:*** | | | | |
| ***Date Actions/Escalations Resolved (if applicable):*** | |  | | |
| ***Signature and Date (SRA/RM-ATMP):*** | |  | | |