**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):*** |  |