**Site Feasibility Questionnaire**

***[NOTE TO SRA/RM-ATMP BEFORE SENDING THIS FORM TO CI/PIs: There are Standard Compulsory Feasibility Questions in Section 1, General Trial Specific Questions in Section 2 and subsequent Trial Specific Sub-sections. Please add relevant/delete irrelevant trial specific questions in Section 2, and delete any Trial Specific Sub-sections not applicable for your trial. A copy of the current PI Oversight form/UK Regulation Compliance form (PART 2) must be sent with this questionnaire if central monitoring is planned/expected (see section 2 question 2). Please ensure the red text is deleted and any blue text is updated before sending it to sites.]***

*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:**

**Name of Site:**

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| **Contact Details** | | | |
| **Principal Investigator** | Name: | |  |
| Address: | |  |
| Contact number: | |  |
| Email: | |  |
| **Sub-Investigator /**  **Co-Investigator** | Name: | |  |
| Address (if different to PI): | |  |
| Contact Number: | |  |
| Email: | |  |
| **Research Nurse /**  **Site Co-ordinator** | Name: | |  |
| Address: | |  |
| Contact number: | |  |
| Email: | |  |
| **Trials Pharmacist**  ***(if applicable)*** | Name: | |  |
| Address: | |  |
| Contact number: | |  |
| Email: | |  |
| **Person responsible for your R&D confirmation of Capacity and Capability?** | | Name: |  |
| Job Title: |  |
| Address: |  |
| Contact number: |  |
| Email: |  |
| **Person responsible for clinical trials agreements** | | Name: |  |
| Job Title: |  |
| Address: |  |
| Contact number: |  |
| Email: |  |
| **Lab contact**  ***(if applicable)*** | | Name: |  |
| Job Title: |  |
| Address: |  |
| Contact number: |  |
| Email: |  |
| **Other contacts**  ***(if applicable)*** | | Name: |  |
| Job Title: |  |
| Address: |  |
| Contact number: |  |
|  | | Email: |  |

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| **SECTION 1: Compulsory Feasibility Questions** | | | | | | |
| 1. How many potential patients do you see per year for this patient group? |  | | *per year OR* | |  | *per month* |
| 1. How many of these patients would be potentially eligible for the study? |  | | | | | |
| 1. How many patients do you think you can recruit to the study per month or year? |  | | *per year OR* | |  | *per month* |
| 1. Do you anticipate any problems recruiting to this trial? | Yes  No | If yes specify reason:­­­­­ | | | | |
| 1. Are you taking part in any other studies in this therapeutic area? | Yes  No | If yes, specify: | | | | |
| 1. Do you have experience working with the IMP? | Yes  No | If yes, specify: | | | | |
| 1. Do you have any or plan to open any trials that may compete with your participation in this study? | Yes  No | If yes, add detail: | | | | |
| 1. Have you been PI on a commercial CTIMP previously? | Yes  No | If yes, how many: | | | | |
| 1. Have you been PI on a non-commercial CTIMP previously? | Yes  No | If yes, how many: | | | | |
| 1. Can you confirm that you have the time and resources to dedicate to participating in this clinical trial? | Yes  No | | | | | |
| 1. Do you and all delegated staff who would be involved in the trial, hold a valid (within 2 years) GCP training certificate prior to the commencement of the trial at site? | Yes, please move on to question 13.  No, please answer question 12. | | | | | |
| 1. Do you follow your institutional policy that allows GCP training to occur more than every 2 years? | Yes. If yes, please provide as attachments  No. If no, please ensure that a valid GCP training certificate is obtained prior to the commencement of this study.  N/A as ticked ‘Yes’ for Question 11. | | | | | |
| 1. Are you currently the PI for any other clinical trials of IMPs? | Yes  No | If yes, how many: | | | | |
| 1. Is there a dedicated study team available for this study? (e.g. a trial co-ordinator, research nurse, data manager?) | Yes  No | If yes, please specify: | | | | |
| 1. Do you have a dedicated clinical trials pharmacy team? | Yes If yes, please complete pharmacy site assessment questionnaire  No | | | | | |
| 1. Do you have access to all trial specific equipment required as per protocol? | Yes  No | If yes, please specify: | | | | |
| 1. Are you using electronic medical records? | Yes  No |  | | | | |
| 1. If no to Question 17, will you be moving from paper to electronic medical records? | Yes  No | If yes, when? | | | | |
| 1. Do you have access to facilities to enable archiving of Investigator site file for 25 years (CTIMPS trials) or 30 years (ATIMPs trials)? | Yes  No | | | | | |
| 1. Please list any Serious breaches that you have reported in the past (please attach additional sheet if necessary). | Attached  None | | | | | |
| 1. Do you have experience of reporting urgent safety measures? | Yes  No | If yes, how many and when? | | | | |
| 1. Are your local laboratories accredited? | Yes  No  N/A - study does  not involve local labs | | | If yes, please specify which laboratories and provide accreditation certificate(s): | | |
| 1. Are your local laboratories able to process and store samples as per the requirements of the protocol and the UK Regulations for GCP? | Yes  No  N/A - study does  not involve local labs | | | If yes, please specify laboratories undertaking processing/storing: | | |
| 1. Are you able to process and ship samples to the central laboratory as per the requirements of the protocol and the UK Regulations for GCP? | Yes  No  N/A - study does not involve central labs | | | | | |

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| **SECTION 2: General Trial Specific Questions** | | |
| 1. As this is a dose escalation study, do you have an SOP for the trust on dose escalation? | Yes - please provide a copy of this SOP  No | |
| 1. If study involves central monitoring, this trial will require the completion of a Compliance Form for the duration of the trial, every 2 months and sent to the sponsor as outlined in the monitoring plan. Will you and your team have the time and resource to complete it? (Please refer to the Compliance Form Pt 2 template attached) | Yes  No  N/A – this study does not involve central monitoring | |
| 1. If this is the CI site for a multi-site study that involves central monitoring, will you and your team have the time and resource to collate the Compliance Forms from participating sites and review (and sign) them all with the JRO? | Yes  No  N/A - not the CI site, this is a PI site. | |
| 1. If the study involves on site monitoring, does your facility have the capacity to host the visit and will you and your team have the resources to respond to monitoring actions in the subsequent Monitoring Visit Report? | Yes  No  N/A – this study does not involve on site monitoring | |
| 1. Do you have 24-hour cover for un-blinding/code breaking? | Yes  No  N/A – open label study | |
| 1. Other trial specific requirements [\*SRAs/RM-ATMPs to add] | Yes  No | If yes, please specify: |

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| **SECTION 3: FTIMP/Phase 1 Trial specific questions** | | | |
| 1. As this is a phase I/ first in man trial, please confirm arrangements and procedures for Medical Emergencies and Facilities at site (including relevant and recent experience of handling medical emergencies, Advanced Life Support and Immediate Life Support training) |  | | |
| 1. Does the site have procedures in place to cover out-of-hours medical emergencies in phase I or first-in-man trials? | Yes  No | If yes, please specify: | |
| 1. As this is a phase I/ first in man trial, for dosing days, will the site be able to provide medical doctors who are trained in GCP, the protocol and have relevant and recent experience of handling medical emergencies or can the trial team rely on the Hospitals resuscitation team in an emergency? | Yes  No | If yes, please specify: | |
| 1. As this is a phase I/ first in man trial, does the site ensure the research team conduct regular emergency simulation training (such as cardiac arrest, anaphylaxis etc.) to be sure that those who do not handle medical emergencies on a regular daily basis maintain their knowledge and skills? | Yes  No | If yes, please specify: | |
| 1. As this is a phase I/ first in man trial, please confirm if there is access to emergency trolleys that have contents in line with current resuscitation council UK guidelines. | Yes  No | | |
| 1. As this is a phase I/ first in man trial, does the site have procedures in place to cover the transfer of a patient to hospital and ensure that the treating physician has appropriate information about the IMP, the clinical trial and next of kin details? | Yes  No | If yes, please specify: | |
| 1. As this is a phase I/ first in man trial of healthy volunteers, does the site have formal procedures in place to minimise the risk of over-volunteering? | Yes  No  N/A – does not involve  healthy volunteers | | If yes, Please specify: |
| 1. As this is a phase I/ first in man trial, is there suitable medical cover at site who are experienced in CTIMPs (preferably Phase I) in case of unexpected absence? | Yes  No | If yes, please specify: | |
| 1. Have you been granted MHRA Phase I accreditation? | Yes - Please provide accreditation certificate  No | | |

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| **SECTION 4: Advanced Therapy Medicinal Product (ATMP) Trial Specific Questions** | | | | | | | | | | | | | | |
| **ATIMP Receipt, Handling, and Storage**  **Please Note:** **A named individual will need to be available to take delivery of each batch of IMP at site. Individuals carrying out tasks related to IMP receipt, handling, storage, administration must be trained to carry out the tasks and delegated by the PI** | | | | | | | | | | | | | | |
| ATIMP: |  | | | | | | | | | | | | | |
| ATIMP Type: | Gene Therapy | | | | | Cell Therapy | | | | Tissue Engineered Product | | | | Combined ATMP |
| **ATIMP Receipt at Site** | | | | | | | | | | | | | | |
| Name the main person responsible for ATMP receipt and storage at site: | Name: | | |  | | | | | | | Job title: |  | | |
| Telephone: | | |  | | | | | | | Email: |  | | |
| Named Individual to receive and handle IMP at site (if known)? | Name: | | |  | | | | | | | Job title: |  | | |
| Telephone: | | |  | | | | | | | Email: |  | | |
| Specify exact location of ATIMP delivery at site : |  | | | | | | | | | | | | | |
| Specify days and times available for delivery if known (e.g. Monday to Friday, 9-5pm): |  | | | | | | | | | | | | | |
| **ATIMP Handling, Reconstitution and Storage at Site** | | | | | | | | | | | | | | |
| Facilities required for Storage / Transport / Handling ATIMP/ATIMP Reconstitution | Include details of storage facilities and/or transport containers required at site (e.g. liquid Nitrogen Dewar, liquid Nitrogen Tank to store Cell Therapy/Gene Therapy/Tissue Engineered product, -80 freezer, -20 Freezer, Fridge, Microbiological Safety Cabinet, liquid Nitrogen, dry ice). Storage conditions required (e.g. temperature, must be reconstituted and given within 2 hours) and any other known specifics regarding the product handling/storage/reconstitution (e.g. biosafety cabinet required for reconstitution) – *Expand/Delete as appropriate* | | | | | | | | | | | | | |
| Do you have the facilities as specified above available at site? | Yes  No | | Comment: | | | | | | | | | | | |
| Will you be able to reconstitute the ATIMP at site? | Yes  No | | Comment: | | | | | | | | | | | |
| Do you have procedures in place at site for the ATIMP handling?  Add details of any site specific procedures which may be required at site in relation to the requirements specified for the ATIMP. *Add/Delete as appropriate.* | a) Transporting Cellular products within the hospital by Liquid Nitrogen Dewar | | | | | | Yes  No | | Comment: | | | | | |
| b) Freezer/LqN2 Tank Temperature Alarm Call out | | | | | | Yes  No | | Comment: | | | | | |
| c) Storage and handling of Gene therapy Products | | | | | | Yes  No | | Comment: | | | | | |
| Storage time period required? | Detail how long the site is likely to have to store the product prior to administration. e.g. The ATIMP will arrive at site up to xxx hours/days prior to required administration | | | | | | Do you have the facilities to store the product for the specified time period?  Yes No | | | | | | | |
| Comment: | | | | | | | |
| Specify EXACT storage location of ATIMP at site if known (include full address including ward or department): |  | | | | | | | | | | | | | |
| Is the storage location secured (e.g. locked or controlled access room, locked freezer) and who has access to the storage location? | Yes  No | Who has access? | | | | | | | | | | | | |
| How will the product be segregated/separated from other IMPs, products or samples?  If cold chain storage is required also specify segregation within the fridge/freezer/tank. |  | | | | | | | | | | | | | |
| **Assessment of ATIMP receipt, storage and handling at site**  You will be required to ensure that the storage location at site is suitable for the product. Ideally a pharmacist or other specialist (i.e. Bone Marrow laboratory / HTA licence QA specialist) should review and approve the receipt and storage location and procedures for the ATIMP. The pharmacy department must be made aware that this is an investigational medicinal product which will be coming into the Trust to ensure their oversight even if not stored in pharmacy. | | | | | | | | | | | | | | |
| Please provide the contact details of the applicable person in your organisation and indicate whether this assessment has been carried out. | Name: | | | | | |  | | | | Job Title: | |  | |
| Telephone: | | | | | |  | | | | Email: | |  | |
| Assessment complete?  Yes No | | | | | | Comment: | | | | | | | |
| Have pharmacy at site been notified of this trial and been provided details of the planned ATIMP management? | Yes No | | | | | | Comment: | | | | | | | |
| Name and job title of pharmacy contact: | | | | | |  | | | | | | | |
| **ATIMP Temperature Control and Monitoring at site** | | | | | | | | | | | | | | |
| How is the storage Location Temperature controlled (if there is no temperature control, please specify)? |  | | | | | | | | | | | | | |
| How is the Storage Location Temperature Monitored? | Manually | | | | | | How often is the temperature recorded (e.g. once a day)? | | | | | | | |
| Are you able to get copies of these temperature records for the TMF? | | | | | | | |
| Continuous Digital Monitoring | | | | | | How often does the device record the temperature? | | | | | | | |
| Is it possible to obtain records of the monitoring for all time periods? | | | | | | | |
| **ATIMP Traceability Records**  *EU ATMP Regulations No 1394/2007 require that clinical trials sites have a system in place for traceability of the patient and the product and retain traceability records for thirty (30) years after the expiry of the ATMP product* | | | | | | | | | | | | | | |
| Are there appropriate archiving facilities available for your site to store trial documents related to traceability of the advanced therapy medicinal products (ATMP) for a minimum of thirty (30) years after completion of the trial at your Site? | | | | | Yes  No | | | Comment: | | | | | | |

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| **Gene Therapy Product Specific Requirements**  **The gene therapy medicinal product Specify product name is considered a genetically modified organism (GMO) and falls under the Genetically Modified Organisms (contained Use regulations 2014) / Genetically Modified Organisms (Deliberate release regulations 2002) as amended and will be regulated by the Health and Safety Executive (HSE) / DEFRA** | | |
| **HSE Notifications**  Anotification to the HSE of first use of premises for GMO activities is required, this includes NHS Trusts where patients will be treated with gene therapy products. | | |
| Is the site notified to the HSE for use of GMOs (first use of premises notification)? | Yes | Date: |
| No | Comment: |
| If a class 2 activity, has a notification to the HSE been submitted and acknowledged?  ***Delete if question not applicable*** | Yes  No | Date: |
| **Institutional Gene Modification Safety Committee (GMSC)**  (Please Note: A written approval/recommendation from this committee is required prior to Trial initiation at Site) | | |
| Does your Site have a local **Gene Modification Safety Committee** in place to evaluate the risk of the gene therapy medicinal product? | Yes | A risk assessment must be carried out and reviewed/approved by the committee prior to the study start |
| No | A committee or individual with expertise in risk assessment relating to contained use must be in place to assess and approve the activity at site prior to study start. Where the risk assessment indicates that the contained use is classified as class 2 or above the advice must be obtained from a genetic modification safety committee |
| If yes, have you already received **approval** from the Committee to carry out the Trial? | Yes  No | |
| Specific requirements for Storage / Transport / Handling the ATIMP which is a GMO | **Include details of: segregation of products, specific equipment or requirements for transporting the product within the hospital, specific spill kits or disinfectant required, protective clothing requirements, specific disposal/decontamination requirements, emergency procedures which may need to be in place. *Expand/Delete as appropriate*** | |
| Do you have the facilities and/or procedures in place to handle gene therapy products as set out above? | Yes  No | |

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| **Donated Tissues/Cells - HTA Requirements**  Donated specify tissues/cells to be procured at site will form the starting materials for the ATIMP. The EU Tissues and Cells directives will apply.  **An HTA human application licence will be required to procure the tissues/cells, carry out donor virology testing and for storage (if >48h).** | | | | | |
| Where at Site is the specify tissues/cells to be procured?Give full address, including ward or clinic name (if known): |  | | | | |
| Does this location have a HTA human application license to procure human tissue/cells for human application? | Yes | Comment: | | | |
| HTA License Number: |  | | Name Designated Individual: |  |
| Telephone: |  | | Email: |  |
| Which laboratory will carry-out the required donor virology testing (HBV, HCV, HIV 1 and 2 syphilis and HTLV)? | Full address: | | | | |
| Does this laboratory have an HTA human application license to test donor samples? | Yes | Comment: | | | |
| HTA License Number: |  | | Name Designated Individual |  |
| Telephone: |  | | Email: |  |
| Where at Site will the specify tissues/cells to be procured be stored, if at all, prior to transport to manufacturing facility?Give full address, including ward or clinic name *(if applicable)*: |  | | | | |
| Is there an HTA human application license in place to store human tissues and cells for human application?  \* only required where tissue or cells, are stored for more than 48 hrs under appropriate controlled conditions until distribution. | Yes No  Not stored  for > 48hrs at site | | Comment: | | |
| HTA License Number: |  | | Name Designated Individual: |  |
| Telephone: |  | | Email: |  |
| Has the Designated individual(s) confirmed that procurement and donor testing and storage if applicable of the specify tissues/cells to be procured for this trial can take place under the licenses specified above? | Yes  No | Comment: | | | |

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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:*** |  | ***Date:*** |  |
| ***Comments:*** | | | | | | |
| ***Actions/Escalation Required:*** | | | | | | |
| ***Responses to Actions/Escalations Required:*** | | | | | | |
| ***Date Actions/Escalations Resolved (if applicable):*** | |  | | | | |
| ***Signature and Date (SRA/RM-ATMP):*** | |  | | | | |