\*\***PLEASE NOTE - ACTION REQUIRED BEFORE SENDING TO SITE**\*\*

This questionnaire must be made study specific. For trials subject to combined risk assessment (SOP GS002) please ensure you have agreed the content of the study specific questionnaire with the Sponsor representative before use.

*Please remove this statement from the final questionnaire version*

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| SECTION 1: Feasibility Assessment |
| SITE INFORMATION |
| Institution | Please enter name of institution | Type of Site | NHS / Non-NHS |
| Site Address | Address Line 1 |  |  |
|  | Address Line 2 | Contact | Please enter name of main site contact |
|  | Town or City | Telephone | Main contact telephone number |
|  | Postcode | Email | Main contact email |

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| PRINCIPAL INVESTIGATOR INFORMATION |
| PI Name | Please enter PI name | Telephone | Enter PI contact number |
|  Email | Enter PI email address |
| 1. Does the PI have experience of being a PI on a CTIMP study in the past 3 years?
 | Yes / No |
| 1. What percentage of the PIs time can be dedicate to this trial?
 | Enter % |
| 1. Does the PI have current GCP training?
 | Yes / No |
| 1. Is the PI based at the site detailed above?
 | Yes / No | If no please state % of time spent at site  | Enter % |
| *Please enclose a copy of PI’s current CV and GCP when returning this questionnaire* |

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| SITE RESOURCES |
| 1. Will there be a research nurse/study coordinator at site?
 | Yes / No |
| 1. If yes please confirm what % of their time will be dedicated to this trial
 | Enter % |
| 1. Will there be involvement from a Clinical Research Facility at site?
 | Yes / No |
| 1. Is there a dedicated Clinical Trials Pharmacy on site? *(Remove this question if no clinical trial pharmacy involvement)*
 | Yes / No | Pharmacy email | Enter email address |

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| RECRUITMENT |
| 1. What is the total population seen at this site for patients with the target condition for this study protocol on an annual basis?
 | Number of patients  |
| 1. How many of these participants do you estimate will meet the protocol defined eligibility criteria?
 | Number of eligible patients |
| 1. Are there any clinical trials currently running or planned at site which could compete for the same patient population?
 | Yes / No | If yes please list name of competing trial |
| 1. Based on the information above how many patients do you realistically expect to enrol on an annual basis?
 | Number of recruits |
| 1. Do you foresee any challenges or risks regarding recruitment and retention for this study at site?
 | Yes / No | If yes please specify |

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| SITE FACILITIES |
| 1. Are there any test included in the protocol which are not standard of care at this site (see protocol table XX)?
 | Yes / No |
| 1. If yes please list
 | List tests which are not standard care at site |
| 1. Are there any aspects of the protocol which will be difficult to complete at this site?
 | Yes / No |
| 1. If yes please list
 | Enter tasks which are difficult to complete at site |
| 1. Are the tasks listed above regularly outsourced by this site?
 | Yes / No |
| 1. If yes please state where
 | Company name | Is there a contract in place for this service? | Yes / No |
| 1. Does the site have the following specialist equipment required to deliver the trial:

List Specialist equipment – *remove question if none* | Yes / No | If no please give details |
| 1. Does the site have experience of using the IMP in the protocol defined patient population as part of clinical care? *For multiple IMPs separate out into multiple questions*
 | Yes / No |
| 1. What format are the medical records at site?
 | Electronic / Paper / Hybrid |
| If electronic health record (EHR) system is in use please record name (if more than one system please list)  | Enter name of EHR system(s) in use at site |
| * 1. Is there direct access to the EHR by external parties for onsite monitoring?
 | Yes / No |
| * 1. Is there an audit trail built into the EHR which is turned on and viewable?
 | Yes / No |
| 1. Does the site have the facilities required for collecting, storing and processing the biological samples required by the protocol?

List specific samples and facilities required – *remove question if none* | Yes / No | If no please give details |
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| 1. Does the site have the laboratory facilities to perform site level analysis of the biological samples required by the protocol?

List specific samples if appropriate – *remove question if none** 1. Is the site laboratory planned to analyse the samples accredited by UKAS (United Kingdom Accreditation Service)? *Only required if samples relate to safety or endpoint data – if not please remove question*
	2. If yes, please record the UKAS accreditation number and name of the laboratory, as stated on the UKAS accreditation.
 | Yes / NoUKAS accreditation number:Laboratory name: |
| 1. Is there a local process for pharmacy to risk assess external IMP storage area? (*Remove this question if IMP will not be stored out with pharmacy)*
 | Yes / No |

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| SIGNATURE |
| To the best of my knowledge the information contained within this questionnaire is correct  |
| Feasibility assessment completed by  | Name  | Position |
| Signature |  | Date |

*Thank you for taking the time to complete this questionnaire*.

*Please return the completed questionnaire to XX*

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| SECTION 2:FOR TRIAL MANAGEMENT USE ONLY |
| Site suitability assessment | Please select one |
| The site meets the pre-defined criteria and will be taken forward  | [ ]  |
| The site does not meet the pre-defined criteria but is able to obtain these with additional support | [ ]  |
| The site does not meet the pre-defined criteria and will not be taken forward  | [ ]  |
| Assessment made by |  | Position |  |
| Signature |  | Date |  |

*Please return the completed questionnaire and site assessment to* *resgov@accord.scot*

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| SECTION 3:FOR SPONSOR USE ONLY |
| Sponsor site suitability review | Please select one |
| Site suitability review completed, site accepted | [ ]  |
| Site suitability review completed, site rejected | [ ]  |
| Site suitability review not required as CI, or designee, has selected not to take site forward | [ ]  |
| Where site suitability review completed | Yes | N/A |
| Any outsourcing of trial procedures/additional vendors flagged to QA | [ ]  | [ ]  |
| Any un-accredited labs (or currently unable to provide UKAS accreditation information) analysing safety or endpoint samples flagged to QA | [ ]  | [ ]  |
| Comments: |
| Sponsor Review completed by |  | Position |  |
| Signature |  | Date |  |

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| SECTION 4:FOR MONITORING USE ONLY (Complete only where risk indicator tool is in use) |
| Site Specific risk level assigned *(low, medium or high according to GS013-T02)* |  |
| Risk level assessed by |  | Position |  |
| Signature |  | Date |  |