Monitoring Plan

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| **Study Details** | | | | | | | |
| Study name |  | | | | | | |
| Type of study |  | | | | | | |
| REC reference |  | | Lothian R&D reference | |  | | |
| Edition of study monitoring plan |  | | Date |  | | Expiry  date |  |
| Previous editions/dates of monitoring plan |  | | | | | | |
| If an update to existing monitoring plan, is this a routine update? If not, provide details | |  | | | | | |

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| **Bespoke Reports** | |
| SIV Report | |
| If bespoke, edition/date |  |
| Previous editions/dates if used |  |
| Monitoring Visit Report | |
| If bespoke, edition/date |  |
| Previous editions/dates if used |  |

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| **Contacts** | |
| CI name |  |
| CI contact details |  |
| Trial Manager/ main study contact |  |
| Lead ACCORD monitor |  |

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| **Study Site** | **Address**  **(For contact info please see**  **contact details spreadsheet)** | **Expected Participant Numbers** |
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|  | Total: |  |

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| **Study Site** | **Supporting Department** | **Contact Information and Address** | |
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| (ü) | | Yes | N/A |
| QA has been informed of the location of all labs that will be involved with the study. | |  |  |

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| **Topic** | **Outcome** | **Level of Monitoring Required**  **As documented on the combined risk assessment tool** | | |
| Reduced | Regular | Increased |
| IMP/agent | Dose Assessment |  |  |  |
| AE Assessment |  |  |  |
| IMP Accountability |  |  |  |
| IMP Storage |  |  |  |
| Study participants | Participant eligibility |  |  |  |
| Participant calendar |  |  |  |
| Participant consent |  |  |  |
| Study design & methods | Data QC checks |  |  |  |
| CRF Completion |  |  |  |
| Protocol/Regulatory Compliance |  |  |  |
| SDV of Outcomes |  |  |  |
| Study organisation | Staff Training |  |  |  |
| Recruitment Reporting |  |  |  |
| Facilities & Resources |  |  |  |
| Records & Delegation |  |  |  |

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| **Expected Monitoring Frequency** |
| Give a brief description of onsite and remote monitoring visits and proposed time points for visits (To be made study specific) |
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| Site Initiation Visits  Each site will have an SIV.  Remote SIVs can be conducted for sites where justification can be provided. This will be recorded in the SIV report. |
| First Monitoring Visit  Onsite Monitoring:  Remote monitoring: |
| Subsequent Monitoring Visits  Onsite Monitoring:  Remote monitoring: |
| Triggered Monitoring Visits  An onsite triggered monitoring visit will be conducted where an issue is identified by the Sponsor, trial team or during remote monitoring which cannot be resolved without onsite investigation.  Triggers will include but are not limited to:   * Evidence of significant under/incorrect reporting of safety events * Serious breach of the protocol or GCP * Evidence of research misconduct * Evidence of significant under/incorrect reporting of protocol non-compliances |
| Close Out Visit  Each site will receive a COV when end of study is reached at site.  Remote Monitoring:  Remote COVs will be conducted where all requirements can be verified remotely.  Onsite Monitoring: |

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| **Timeframes** | | | |
| SIV Report | | | |
| Timeline for report completion | 5 working days from completion of monitoring visit | | |
| Review required? | YES | Reviewer  (if required) | Senior Clinical Trials Monitor or Designee |
| Timeline for review completion | 3 working days from receipt of draft report | | |
| Timeline for submission to PI after review completion (urgent issues escalated immediately) | 2 working days from receipt of completed review | | |
| SATO | | | |
| Timeline for SATO completion | 3 months from SIV | | |
| Review required? | YES | Reviewer  (if required) | Senior Clinical Trials Monitor or Designee |
| Timeline for review completion | 3 working days from receipt of draft SATO | | |
| Timeline for submission to PI after review completion (urgent issues escalated immediately) | 2 working days from completion of review | | |
| Monitoring Visit Report | | | |
| Timeline for report completion | 5 working days from completion of visit | | |
| Review required? | YES | Reviewer  (if required) | Senior Clinical Trials Monitor or Designee |
| Timeline for review completion | 3 working days from receipt of draft report | | |
| Timeline for submission of follow up letter to PI after review completion (urgent issues escalated immediately) | 2 working days from completion of review | | |
| Close Out Visit Report | | | |
| Timeline for report completion | 5 working days from completion of visit | | |
| Review required? | YES | Reviewer  (if required) | Senior Clinical Trials Monitor or Designee |
| Timeline for review completion | 3 working days from receipt of draft report | | |
| Timeline for submission of follow up letter to PI after review completion (urgent issues escalated immediately) | 2 working days from completion of review | | |
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| **Screening & Recruitment Figure Reporting** | |
| Sponsor | |
| Timeline for reporting |  |

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| **Blinding** | | | |
| (ü) | | Yes | No |
| Blinded study | |  |  |
| If yes, are aspects of the study unblinded *(e.g pharmacy or IMP administration)* | |  |  |
| If yes, detail study specific monitoring requirements to prevent bias |  | | |

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| **Management Strategy** |
| Record management strategy comments as documented in the combined risk assessment tool (e.g. – Monitoring of IMP storage conditions not required) |
| General Strategies |
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| Site Initiation Visit |
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| Monitoring Visits (first visit, subsequent visits) |
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| Triggered Monitoring Visits |
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| Close Out Visits |
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| **Delegated Monitoring Tasks** | |
| Record all tasks delegated from the ACCORD monitoring team and clearly document to who these tasks are delegated (e.g. – Performance of onsite SIVs delegated to Trial Manager) | |
| Delegated Task | Designee |
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| **Designee Statement of Understanding** | |
| I confirm that I understand the tasks delegated from the ACCORD monitoring team to me (or the wider organisation I am a part of). I accept responsibility for the completion of these monitoring tasks (or where wider delegation is required informing others within my organisation of the tasks and training required). I agree to immediately escalate any issues relating to the completion of these tasks to the Senior Clinical Trials Monitor. I also agree to send monitoring reports and follow up letters for review by the Senior Clinical Trials Monitor or designee as required by the monitoring plan. | |
| Delegation accepted by |  |
| Job Function |  |
| Signature |  |
| Date | Click here to enter a date. |
| I confirm that the above designee(s) are appropriately trained in the study protocol, sponsor SOPs and completion of the delegated monitoring tasks. | |
| Delegation confirmed appropriate by |  |
| Job Function |  |
| Signature |  |
| Date | Click here to enter a date. |

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| **Plan Signatures** | | | |
| **Monitoring Plan Completion** | | | |
| Plan completed by |  | Role |  |
| Plan completed date |  | Date plan sent for review |  |
| Signature |  | Date |  |
| **Monitoring Plan Review** | | | |
| Plan Reviewed by |  | Role |  |
| Date plan received for review |  | Date review completed |  |
| Signature |  | Date |  |