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| Study Details | | | |
| Study name |  | | |
| Type of study |  | | |
| REC reference |  | Lothian R&D reference |  |
| Study site |  | | |
| NHS Trust/Health Board |  | | |
| PI name |  | | |
| PI contact details |  | | |

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| Visit Details | | | | | | |
| Date of visit |  | | | | Dates of any pre-SIV meetings |  |
| Type of visit () | Onsite |  | Remote |  | If remote document justification: | |
| ACCORD personnel (or designees) present |  | | | | | |
| Study site personnel present |  | | | | | |
| Visit to supporting departments conducted |  | | | | | |

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| Participant Recruitment | | | | | | |
| Planned date screening to start |  | | | | | |
| Planned First Participant In (FPI) |  | | | | | |
| Planned Last Participant In (LPI) |  | | | | | |
| Recruitment targets and methods |  | | | | | |
| Describe any barriers to recruitment identified |  | | | | | |
| Feasibility questionnaire complete and any issues discussed () | Yes |  | No |  | If no, please state reason |  |
| Will site recruit from more than 1 hospital within NHS Board/Trust () | Yes |  | No |  | If yes please list additional hospital(s) |  |
| If yes please document which study activities will be carried out at additional hospital(s) and logistics (e.g where study documentation will be held, IMP supplied from, any differences in processes) | | |  | | | |

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| Monitoring Systems | |
| Monitoring Plan version |  |
| SDV Plan version |  |

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| Study Organisation | | | | | | | |
|  | | In place | | | Location held | | |
| Sponsor File | |  | | |  | | |
| Trial Master File | |  | | |  | | |
| Investigator Site File | |  | | |  | | |
| () | | Yes | No | | | N/A | |
| TMF Delegation CR001-F01 in place | |  |  | | |  | |
| () | | Yes | | | No | | |
| Study document tracker updated to show document versions and approval dates | |  | | |  | | |
| Are there any external vendors performing Investigator responsibilities at site (e.g. courier transporting IMP/samples or external imaging facility providing scanning)? | |  | | |  | | |
| If external site level vendors are identified ACCORD QA informed | | | | Yes | | | N/A |
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| Comments: |  | | | | | | |

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| Staff Training | | | | |
| Protocol training | **Training Provided: ** | Training Provided | | |
| Yes | No | N/A |
| Protocol summary |  |  |  |
| Study objectives and design |  |  |  |
| Screening and consent procedure |  |  |  |
| Inclusion/Exclusion criteria |  |  |  |
| Randomisation |  |  |  |
| Co-enrolment |  |  |  |
| Study Procedures |  |  |  |
| Sub-study training |  |  |  |
| Unblinding |  |  |  |
| Comments: |  | | | |

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| Staff Training | | | | |
| SOP training | **Training Provided: ** | Training Provided | | |
| Yes | No | N/A |
| CR001 – Maintaining trial files |  |  |  |
| CR003 – Serious breach of GCP or protocol |  |  |  |
| CR004 – Recording and reporting study data |  |  |  |
| CR005 – AE reporting (CTIMP) |  |  |  |
| CR006 – AE reporting (non-CTIMP) |  |  |  |
| CR007 – Study documents and amendments |  |  |  |
| CR007 – Keeping a delegation log |  |  |  |
| CR007 – Screening and ID logs |  |  |  |
| CR008 – Progress and safety reports |  |  |  |
| CR009 – Study closure and archiving |  |  |  |
| CR010 – Protocol deviations and violations |  |  |  |
| CR011 – CTIMP report preparation |  |  |  |
| CR012 – AE reporting (device trials) |  |  |  |
| CR013 – CRF design and Implementation |  |  |  |
| CR014 – Suspected Research Misconduct |  |  |  |
| CR015 – Trial Committees (DMC/TSC Charters) |  |  |  |
| GS010 – IMP management |  |  |  |
| Policy & Guideline training | Protocol Waivers Policy |  |  |  |
| Co-enrolment policy |  |  |  |
| General training and discussion | PI responsibilities |  |  |  |
| CVs, GCPs and study training documentation |  |  |  |
| CRF completion and timeline for data entry |  |  |  |
| Source data plan (CR004-T01) |  |  |  |
| Testing unblinding procedures prior to SATO |  |  |  |
| Pregnancy and overdose procedures |  |  |  |
| Reference safety information |  |  |  |
| Implementation of amendments |  |  |  |
| IMP accountability |  |  |  |
| Equipment calibration and accountability |  |  |  |
| Site archiving responsibilities |  |  |  |
| Informed consent | Documentation required for informed consent discussed |  |  |  |
| Is there a local SOP for Informed consent that will be used in this trial? (If yes obtain a copy and review) |  |  |  |
| eCRF/Database training | Training provided on database/eCRF to site team |  |  |  |
| Comments: |  | | | |

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| Product/Device Accountability and Storage | | | | | | | |
| Storage  () | | Appropriate storage | | | Storage logs in place  (eg Temperature) | | |
| Yes | No | N/A | Yes | No | N/A |
| Study site(s) – storage of IMP/NIMP/Agent/Device  (delete as appropriate) | |  |  |  |  |  |  |
| () | | | | | Yes | No | N/A |
| IMP/agent/device on site at time of SIV? | | | | |  |  |  |
| Accountability tracking in place at pharmacy level | | | | |  |  |  |
| Accountability and prescription approved for use at site | | | | |  |  |  |
| Accountability tracking in place at ward level | | | | |  |  |  |
| Calibration of storage monitoring equipment completed | | | | |  |  |  |
| Comments: |  | | | | | | |

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| Human Biological Samples | | | | |
| () | | Yes | No | N/A |
| Confirmed where samples will be analysed | |  |  |  |
| Confirmed where samples will be stored | |  |  |  |
| Requirement for local SOPs for sample handling | |  |  |  |
| Labels for samples in place | |  |  |  |
| Sample log tracker in place | |  |  |  |
| Calibration of equipment completed | |  |  |  |
| Comments: |  | | | |

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| Other Supporting Departments | | | | |
| Specify Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| () | Yes | No | N/A | Comments |
| Delegation log or equivalent present for supporting department |  |  |  |  |
| Supporting department furnished with documentation of approvals and applicable study materials |  |  |  |  |

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| Other Supporting Departments | | | | |
| Specify Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| () | Yes | No | N/A | Comments |
| Delegation log or equivalent present for supporting department |  |  |  |  |
| Supporting department furnished with documentation of approvals and applicable study materials |  |  |  |  |

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| Source Data Collection | | | |
| Discuss the arrangement for keeping data secure |  | | |
| Format of medical records at site where source data will be captured? (electronic, paper, mixture) |  | | |
| () | Yes | No | N/A |
| If electronic medical notes, will there be a flag to show participants are taking part in a trial? |  |  |  |
| Is there a process in place for monitors to access electronic medical records during monitoring visits? |  |  |  |
| If some of the trial data will be entered directly into the eCRF as source and/or collected away from the site (e.g central questionnaires) , discuss the process in place to return this data to the site at the end of the study and confirm responsibilities for archiving. |  |  |  |
| Comments: |  | | |

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| Final Checklist | | | |
| What plans are in place to ensure adherence to routine GCP training and GCP refresher training |  | | |
| Confirm that site understands timeframes for reporting recruitment to local R&D and sponsor as detailed in the monitoring plan |  | | |
| () | Yes | No | N/A |
| REC approval in place and conditions met? |  |  |  |
| MHRA approval in place and conditions met? |  |  |  |
| Local R&D approval in place and conditions met? |  |  |  |
| Comments: |  | | |

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| Comments and Actions |
| Comments |
|  |
| Actions for Study Team |
|  |
| Actions for ACCORD Monitoring Team |
|  |

NOTE: Transfer actions to monitoring visit action log (CM002-T03) and follow up actions until resolution

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| If SIV cannot be completed, document details of all outstanding items below |
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| SIV Report Signatures | | | |
| **Report Completion** | | | |
| Author of Report: |  | Role: |  |
| Report Completion Date: |  | Date sent for Review: |  |
| Signature: |  | Date: |  |
| **Report Review** (if required by monitoring plan) | | | |
| Reviewer of Report: |  | Role: |  |
| Date Report Received: |  | Date Review Completed: |  |
| Signature: |  | Date: |  |
| **PI Statement** | | | |
| **I agree that I have been trained and understand the Sponsor SOPs and the requirement to conduct this trial in line with the SOPs, ICH GCP and any other regulatory requirements** | | | |
| PI Name: |  | | |
| Signature: |  | Date: |  |