Monitoring Visit Report

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| Study Details | | | | |
| Study name |  | | | |
| Type of study |  | | | |
| REC reference |  | Lothian R&D reference | |  |
| Edition of MV report |  | Date |  | |
| Study Site |  | | | |
| PI name |  | | | |
| PI contact details |  | | | |

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| Visit Details | | | | | | | | | | | |
| Date of visit | Click here to enter a date. | | | | | | Date of last visit | Click here to enter a date. | | | |
| Type of visit (ü) | Onsite | |  | Remote | |  | If remote document justification: | | | | |
| ACCORD personnel present |  | | | | | | | | | | |
| Study personnel present |  | | | | | | | | | | |
| Type of visit (ü) | Routine |  | | Triggered |  | | PI seen (ü) | Yes |  | No |  |
| Visit to supporting departments conducted |  | | | | | | | | | | |

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| Participant Recruitment | | | |
| Date of sponsor authorisation for site |  | | |
| Study timelines |  | | |
| Issues identified via discussion of recruitment with PI |  | | |
|  | Planned | Actual | |
| Pre -Screened |  | |  |
| Consented |  | |  |
| Study Screened |  | |  |
| First Participant In (FPI) date |  | |  |
| Screen Fails | Not relevant | |  |
| Randomised |  | |  |
| Ongoing | Not relevant | |  |
| Completed |  | |  |
| Withdrawn | Not relevant | |  |

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| Monitoring Systems | |
| Monitoring Plan edition |  |
| SDV Plan edition |  |

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| Study Documentation | | | | | | | | | |
|  | | Person responsible | | Location held | | Updates required? (ü) | | | |
| Sponsor File | |  | |  | | Yes | | No | N/A |
|  | |  |  |
| Trial Master File | |  | |  | |  | |  |  |
| Investigator Site File | |  | |  | |  | |  |  |
| (ü) | | | Yes | | No | | N/A | | |
| TMF Delegation CR001-F01 in place | | |  | |  | |  | | |
| Study document tracker updated to show current document versions and approval dates | | |  | |  | |  | | |
| Actions: |  | | | | | | | | |
| Comments: |  | | | | | | | | |

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| Study Blind | | | | |
| (ü) | | Yes | No | N/A |
| Has the blind been maintained in accordance with the study protocol? | |  |  |  |
| Code breaks analysed for appropriateness and maintenance of blind? | |  |  |  |
| Actions: |  | | | |
| Comments: |  | | | |

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| IMP/Agent – Dose Assessment | | | | | |
| (ü) | Yes | No | | N/A | |
| Dose given as per protocol |  |  | |  | |
| Dose recorded in medical notes |  |  | |  | |
| Describe issues identified: |  | | | | |
| SDV Plan (ü) | | | On site | | Remote |
| Monitoring activities completed via | | |  | |  |
| Detail activities performed | | | | | |
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| Comments: |  | | | | |

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| IMP/Agent – AE Assessment | | | | |  |
| (ü) | | Yes | No | | N/A |
| Site records of AEs (SAEs/SUSARs/pregnancy) reconciled with ACCORD PV database | |  |  | |  |
| Compliance with expedited and onward reporting requirements as specified in the site agreement has been confirmed | |  |  | |  |
| Reference safety information is up to date and documented evidence is available to confirm that RSI changes have been reviewed and approved by the CI | |  |  | |  |
| Describe issues identified: |  | | | | |
| SDV Plan (ü) | | On site | | Remote | |
| Monitoring activities completed via | |  | |  | |
| Detail activities performed | | | | | |
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| Comments: |  | | | | |

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| IMP/Agent/Device - IMP Accountability | | | | | | | | | |
| Storage | | Appropriate storage | | | Storage logs monitored  (eg Temperature) | | | | |
| (ü) | | Yes | No | N/A | Yes | | No | | N/A |
| Study site(s) where IMP/agent/device stored | |  |  |  |  | |  | |  |
| Pharmacy | |  |  |  |  | |  | |  |
| IMP/Agent/Device Checklist (ü) | | | | | Yes | | No | | N/A |
| Expiry date checked | | | | |  | |  | |  |
| Followed from receipt through to destruction | | | | |  | |  | |  |
| Prescriptions versus accountability checked that administration correct | | | | |  | |  | |  |
| Dispensing procedure correctly followed | | | | |  | |  | |  |
| Pharmacy aware of amendments, file contains current approvals | | | | |  | |  | |  |
| IMP/agent/device stored in a secure location, segregated from other medicines/devices | | | | |  | |  | |  |
| Used and returned IMP/agent/device separate from unused medication/devices | | | | |  | |  | |  |
| IMP/agent/device correctly labelled | | | | |  | |  | |  |
| If IMP/agent stored out with pharmacy, delegation has been documented and storage is correct as per pharmacy agreement | | | | |  | |  | |  |
| IMP/Agent/Device Documentation (ü) | | | | | Yes | | No | | N/A |
| Accountability logs complete | | | | |  | |  | |  |
| Members of staff accountable for IMP/agent/device delegated on appropriate delegation log | | | | |  | |  | |  |
| Actions: |  | | | | | | | | |
| SDV Plan (ü) | | | | | | On site | | Remote | |
| Monitoring activities completed via | | | | | |  | |  | |
| Detail activities performed at pharmacy level | | | | | | | | | |
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| Detail activities performed at ward level | | | | | | | | | |
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| Comments: |  | | | | | | | | |

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| Study Participants – Participant Eligibility | | | |
| (ü) | | Yes | No |
| Confirmation of compliance with screening procedure, as defined in the study protocol | |  |  |
| Describe issues identified: |  | | |
| SDV Plan (ü) | | On site | Remote |
| Monitoring activities completed via | |  |  |
| Detail activities performed | | | |
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| Comments: |  | | |

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| Study Participants – Participant Calendar | | | | |
| (ü) | | Yes | No | N/A |
| Confirmation of compliance with enrolment and randomisation procedures, as defined in the study protocol | |  |  |  |
| Confirmation of compliance with method agreed during the SIV to flag study participants (TRAK, medical notes, etc) | |  |  |  |
| Describe issues identified: |  | | | |
| SDV Plan (ü) | | On site | | Remote |
| Monitoring activities completed via | |  | |  |
| Detail activities performed | | | | |
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| Comments: |  | | | |

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| Study Participants – Participant Consent | | | |
| (ü) | | Yes | No |
| Confirmation of compliance with consent procedure, as defined in the study protocol | |  |  |
| Describe issues identified: |  | | |
| SDV Plan (ü) | | On site | Remote |
| Monitoring activities completed via | |  |  |
| Detail activities performed | | | |
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| Comments: |  | | |

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| Study Design and Methods – Data QC Checks | | | |
| Describe issues identified: |  | | |
| SDV Plan (ü) | | On site | Remote |
| Monitoring activities completed via | |  |  |
| Detail activities performed | | | |
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| Comments: |  | | |

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| Study Design and Methods – CRF Completion | | | |
| (ü) | | Yes | No |
| Confirmation of compliance with agreed timeframes for data entry into CRFs | |  |  |
| CRF version correct and CRF tracker up to date | |  |  |
| Audit Trail Review Performed | |  |  |
| Describe issues identified: |  | | |
| SDV Plan (ü) | | On site | Remote |
| Monitoring activities completed via | |  |  |
| Detail activities performed | | | |
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| Comments: |  | | |

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| Study Design and Methods – Protocol/Regulatory Compliance | | | |
| (ü) | | Yes | No |
| Site deviation log reconciled with sponsor records | |  |  |
| Site violation log reconciled with sponsor records | |  |  |
| Confirmation of compliance with deviation reporting frequency | |  |  |
| Describe issues identified: |  | | |
| SDV Plan (ü) | | On site | Remote |
| Monitoring activities completed via | |  |  |
| Detail activities performed | | | |
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| Comments: |  | | |

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| Study Design and Methods – SDV of Outcomes | | | |
| Describe issues identified: |  | | |
| SDV Plan (ü) | | On site | Remote |
| Monitoring activities completed via | |  |  |
| Detail activities performed | | | |
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| Comments: |  | | |

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| Study Organisation – Staff Training | | | |
| (ü) | | Yes | No |
| Are CVs and GCP training up to date for all members of staff? | |  |  |
| Any training requirements identified? | |  |  |
| Describe issues identified: |  | | |
| SDV Plan (ü) | | On site | Remote |
| Monitoring activities completed via | |  |  |
| Detail activities performed | | | |
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| Comments: |  | | |

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| Study Organisation – Recruitment Reporting | | | | | |
| (ü) | | Yes | No | | N/A |
| Compliance with recruitment reporting timelines | |  |  | |  |
| Describe issues identified: |  | | | | |
| SDV Plan (ü) | | On site | | Remote | |
| Monitoring activities completed via | |  | |  | |
| Detail activities performed | | | | | |
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| Comments: |  | | | | |

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| Study Organisation – Facilities & Resources | | | | | | | |
| Human Biological Samples | | | | | | | |
| (ü) | | Yes | No | N/A | Comments | | |
| Sample storage checked | |  |  |  |  | | |
| Collection, location and storage logs checked | |  |  |  |  | | |
| Lab accreditations/QA audit in place | |  |  |  |  | | |
| Specify Supporting Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | |
| (ü) | | Yes | No | N/A | Comments | | |
| Local R&D approval for supporting departments involvement | |  |  |  |  | | |
| Delegation log present | |  |  |  |  | | |
| Study approvals up to date | |  |  |  |  | | |
| Specify Supporting Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | |
| (ü) | | Yes | No | N/A | Comments | | |
| Local R&D approval for supporting departments involvement | |  |  |  |  | | |
| Delegation log present | |  |  |  |  | | |
| Study approvals up to date | |  |  |  |  | | |
| SDV Plan (ü) | | | | | | On site | Remote |
| Monitoring activities completed via | | | | | |  |  |
| Detail activities performed | | | | | | | |
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| Comments: |  | | | | | | |

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| Study Organisation – Records & Delegation | | | |
| (ü) | | Yes | No |
| Delegation log up to date? | |  |  |
| Are there any new members added to research team since last visit? | |  |  |
| Describe issues identified: |  | | |
| SDV Plan (ü) | | On site | Remote |
| Monitoring activities completed via | | ☐ | ☐ |
| Detail activities performed | | | |
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| Comments: |  | | |

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| Comments and Actions |
| If MV cannot be completed, document details of all outstanding items below |
|  |
| Actions for study team |
|  |
| Actions for ACCORD monitoring team |
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NOTE: Transfer actions to monitoring visit action log (CM002-T03) and follow up actions until resolution

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| MV Report Signatures | | | |
| **Report Completion** | | | |
| Author of Report: |  | Role: |  |
| Report Completion Date: | Click here to enter a date. | Date sent for Review: | Click here to enter a date. |
| Signature: |  | Date: | Click here to enter a date. |
| **Report Review (**if required by monitoring plan) | | | |
| Reviewer of Report: |  | Role: |  |
| Date Report Received: | Click here to enter a date. | Date Review Completed: | Click here to enter a date. |
| Signature: |  | Date: | Click here to enter a date. |

Appendix 1

The below tool may be used at the monitor’s discretion

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| SDV performed during monitoring visit | | | | | | | | | | | |
| Patient ID | Status | Consent | Eligibility | Calendar | CRF completion | SDV 1° endpoints | SDV 2° endpoints | AEs | IMP accountability check | IMP dose check | QC checks |
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