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| Withdrawn | Not relevant |  |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 |
|  |
| 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 |
|  |
| 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 |
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| Actions for study team |
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| 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

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| 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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