SDV Plan

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| **Study Details** | | | | | |
| Study name |  | | | | |
| REC reference |  | | Lothian R&D reference | |  |
| Edition of study SDV plan |  | | Date |  | |
| Edition of study monitoring plan |  | | Date |  | |
| Previous editions/dates of SDV plans |  | | | | |
| If an update to existing SDV plan, please provide details | |  | | | |

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| **Study Oversight Committees** | |
| Committee | Planned meeting timeframe & oversight activities  (Monitor to confirm oversight progressing according to study protocol/appropriate charters) |
| Data Monitoring Committee |  |
| Trial Steering Committee |  |
| Planned interim analysis |  |
| Trial Management Group |  |
| Other |  |

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| **Study Files** | | | |
| Document Monitored (✓) | Yes | N/A | Frequency/notes |
| Trial Master File |  |  | e.g. Annually and at COV |
| Investigator Site File |  |  | e.g. At onsite MV and COV |
| Sponsor File |  |  | e.g. Annually |

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| **Completion Guidelines** |
| For all topics and outcomes: Please specify the percentage of participants to be monitored remotely or on site and whether this percentage figure is across all study sites or per site.  E.g. Remote monitoring: For 20% of participants recruited across study sites  Onsite monitoring: For 15% of participants recruited at site  For each ‘Detail activities to be performed’ section please select the wording on the level of monitoring as directed by the monitoring plan/ACCORD Combined Risk Assessment and amended it according to the study protocol requirements. The final wording should reflect the monitoring tasks which will be carried out during the course of the study. These tasks will differ depending on the study design, risk adaption and electronic systems in place. Please ensure tasks listed are feasible. |

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| **IMP/Agent** | | |
| Dose Assessment (✓) | On site | Remote |
| Completion of monitoring activities |  |  |
| Detail activities to be performed (delete/modify as required) | | |
| **Reduced level of monitoring**  **Remote:**   * Study dose may be assessed via eCRFs by clinical monitors. * Sample will be extended to 100% of participants at any site where errors are identified. * If a dosing/dose escalation error is identified in more than 15% of participants at a specific site an onsite visit will be triggered. | | |
| **Regular level of monitoring**  **Remote:**   * Study dose may be assessed via eCRFs by clinical monitors. * Sample will be extended to 100% of participants at any site where errors are identified. * If a dosing/dose escalation error is identified in more than 15% of participants at a specific site an onsite visit will be triggered.   **Onsite:**   * Onsite monitoring for selected participants   + Batch numbers traced from medical notes to pharmacy.   + Study dose compared with medical notes and any randomisation documentation.   + Confirmation 100% of the dose was correct. | | |
| **Increased level of monitoring**  **Remote:**   * Study dose may be assessed via eCRFs by clinical monitors. * Sample will be extended to 100% of participants at any site where errors are identified. * If a dosing/dose escalation error is identified in more than 15% of participants at a specific site an onsite visit will be triggered.   **Onsite:**   * Onsite monitoring for selected participants   + Batch numbers traced from medical notes to pharmacy.   + Study dose compared with medical notes and any randomisation documentation.   + Confirmation 100% of the dose was correct.   + Verification that participants received dosing instructions (if applicable) | | |
| AE Assessment (✓) | On site | Remote |
| Completion of monitoring activities |  |  |
| Detail activities to be performed (delete/modify as required) | | |
| **Reduced level of monitoring**  **Remote:**   * DSURs will describe safety information to maintain oversight. DMC may review safety information. * Clinical Trial Monitor will review documents showing oversight of safety events by DMC/TSC to ensure that the proposed schedule is adhered to. (if applicable) * Remote review of adverse event reporting rates will be conducted annually by review of reported events on the eCRF. * If issues are identified with AE reporting during routine data checks these will be escalated to the lead monitor and/or senior clinical trials monitor. An onsite visit will be triggered in the event significant under/incorrect reporting of AEs is identified. | | |
| **Regular level of monitoring**  **Remote:**   * DSURs will describe safety information to maintain oversight. DMC may review safety information. * Clinical Trial Monitor will review documents showing oversight of safety events by DMC/TSC to ensure that the proposed schedule is adhered to. (if applicable) * Remote review of adverse event reporting rates will be conducted annually by review of reported events on the eCRF. * If issues are identified with AE reporting during routine data checks these will be escalated to the lead monitor and/or senior clinical trials monitor. An onsite visit will be triggered in the event significant under/incorrect reporting of AEs is identified.   **Onsite:**   * Onsite monitoring for selected participants   + Monitors will review medical records or any other applicable records for AEs and ensure that they are recorded, correctly assessed and followed up correctly as per protocol.   + SDV will be performed for all serious events/reactions at site.   This sample size will be increased if errors are observed. | | |
| **Increased level of monitoring**  **Remote:**   * DSURs will describe safety information to maintain oversight. DMC may review safety information. * Clinical Trial Monitor will review documents showing oversight of safety events by DMC/TSC to ensure that the proposed schedule is adhered to. (if applicable) * Remote review of adverse event reporting rates will be conducted annually by review of reported events on the eCRF. * If issues are identified with AE reporting during routine data checks these will be escalated to the lead monitor and/or senior clinical trials monitor. An onsite visit will be triggered in the event significant under/incorrect reporting of AEs is identified.   **Onsite**   * Onsite monitoring for selected participants   + Monitors will review medical records or any other applicable records for AEs and ensure that they are recorded, correctly assessed and followed up correctly as per protocol.   + SDV will be performed for all serious events/reactions at site.   + All AEs will be reviewed.   This sample size will be increased if errors are observed. | | |
| IMP Accountability (✓) | On site | Remote |
| Completion of monitoring activities |  |  |
| Detail activities to be performed (delete/modify as required) | | |
| **Reduced level of monitoring**  **Remote:**   * IMP accountability may be conducted by delegated study team members and pharmacy and reported to monitors. * Batch numbers and expiry dates may be checked by delegated study team members and reported to monitors. * Clinical Trial Monitor may remotely monitor the entry of tablet count by delegated study team members and pharmacy through the eCRF. | | |
| **Regular level of monitoring**  **Remote:**   * IMP accountability may be conducted by delegated study team members and pharmacy and reported to monitors. * Batch numbers and expiry dates may be checked by delegated study team members and reported to monitors. * Clinical Trial Monitor may remotely monitor the entry of tablet count by delegated study team members and pharmacy through the eCRF.   **Onsite:**   * Onsite monitoring   + During routine onsite monitoring, a visit to pharmacy may be conducted to carry out an accountability check of the IMP.   + Batch numbers and expiry dates of any IMP will also be checked for a sample of participants. | | |
| **Increased level of monitoring**  **Remote:**   * IMP accountability may be conducted by delegated study team members and pharmacy and reported to monitors. * Batch numbers and expiry dates may be checked by delegated study team members and reported to monitors. * Clinical Trial Monitor may remotely monitor the entry of tablet count by delegated study team members and pharmacy through the eCRF.   **Onsite:**   * Onsite monitoring   + During routine onsite monitoring, a visit to pharmacy may be conducted to carry out an accountability check of the IMP.   + Record of receipt, dispensation, return and destruction will be reviewed.   Batch numbers and expiry dates of any IMP will also be checked for a sample of participants. | | |
| Detail activities to be performed in pharmacy and at ward level | | |
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| IMP Storage (✓) | On site | Remote |
| Completion of monitoring activities |  |  |
| Detail activities to be performed (delete/modify as required) | | |
| **Reduced level of monitoring**  **Remote**   * Checking temperature logs may be performed by delegated study team members and reported to clinical monitors. | | |
| **Regular level of monitoring**  **Remote:**   * Checking temperature logs may be performed by delegated study team members and reported to clinical monitors.   **Onsite:**   * Onsite monitoring   + Temperature logs will be reviewed at routine monitoring visits to pharmacy. | | |
| **Increased level of monitoring**  **Remote:**   * Checking temperature logs may be performed by delegated study team members and reported to clinical monitors.   **Onsite:**   * Onsite monitoring   + Temperature logs will be reviewed at routine monitoring visits to pharmacy. | | |

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| **Study Participants** | | |
| Participant Eligibility (✓) | On site | Remote |
| Completion of monitoring activities |  |  |
| Detail activities to be performed (delete/modify as required) | | |
| **Reduced level of monitoring**  **Remote:**   * Eligibility can be confirmed remotely via eligibility checklists by a trial manager or clinical monitor. It will be ensured that the checklist has been completed and eligibility signed off by delegated medic. * Eligibility will be checked at telephone monitoring call for sites that require support based on site staff research experience. * If issues are identified with eligibility during the telephone monitoring call, these will be escalated to the lead monitor and/or senior clinical trials monitor. | | |
| **Regular level of monitoring**  **Remote:**   * Eligibility can be confirmed remotely via eligibility checklists by a trial manager or clinical monitor. It will be ensured that the checklist has been completed and eligibility signed off by delegated medic. * Eligibility will be checked at telephone monitoring call for sites that require support based on site staff research experience. * If issues are identified with eligibility during the telephone monitoring call, these will be escalated to the lead monitor and/or senior clinical trials monitor.   **Onsite:**   * Onsite monitoring for selected participants   + Monitors will SDV 100% of eligibility criteria where possible | | |
| **Increased level of monitoring**  **Remote:**   * Eligibility can be confirmed remotely via eligibility checklists by a trial manager or clinical monitor. It will be ensured that the checklist has been completed and eligibility signed off by delegated medic. * Eligibility will be checked at telephone monitoring call for sites that require support based on site staff research experience. * If issues are identified with eligibility during the telephone monitoring call, these will be escalated to the lead monitor and/or senior clinical trials monitor.   **Onsite:**   * Onsite monitoring for selected participants   Monitors will SDV 100% of eligibility criteria where possible | | |
| Participant Calendar (✓) | On site | Remote |
| Completion of monitoring activities |  |  |
| Detail activities to be performed (delete/modify as required) | | |
| **Reduced level of monitoring**  **Remote:**   * Participant attendance may be checked remotely via eCRF by a trial manager or clinical monitor. If issues are identified with participant visits, these will be escalated to the lead monitor and/or senior clinical trials monitor. * Study teams can send deviation logs directly to ACCORD QA to capture when participants have not attended visits. These logs will be reviewed by ACCORD QA on a quarterly basis. | | |
| **Regular level of monitoring**  **Remote:**   * Participant attendance may be checked remotely via eCRF by a trial manager or clinical monitor. If issues are identified with participant visits, these will be escalated to the lead monitor and/or senior clinical trials monitor. * Study teams can send deviation logs directly to ACCORD QA to capture when participants have not attended visits. These logs will be reviewed by ACCORD QA on a quarterly basis.   **Onsite:**   * Onsite monitoring for selected participants   + Monitors will check 100% of attendance data where possible or unless otherwise stated in the monitoring plan. | | |
| **Increased level of monitoring**  **Remote:**   * Participant attendance may be checked remotely via eCRF by a trial manager or clinical monitor. If issues are identified with participant visits, these will be escalated to the lead monitor and/or senior clinical trials monitor. * Study teams can send deviation logs directly to ACCORD QA to capture when participants have not attended visits. These logs will be reviewed by ACCORD QA on a quarterly basis. * Deviation logs will be forwarded to monitors at a greater frequency.   **Onsite:**   * Onsite monitoring for selected participants   Monitors will check 100% of attendance data unless otherwise stated in the monitoring plan. | | |
| Participant Consent (✓) | On site | Remote |
| Completion of monitoring activities |  |  |
| Detail activities to be performed (delete/modify as required) | | |
| **Reduced level of monitoring**  **Remote:**   * Forms may be reviewed remotely by clinical monitors. * Process can be discussed at SIV and at other times if necessary. * Consent process will be checked at telephone monitoring call for sites that require support based on site staff research experience. * If issues are identified with consent process by the trial manager during routine data checks these will be escalated to the lead monitor and/or senior clinical trials monitor. | | |
| **Regular level of monitoring**  **Remote:**   * Forms may be reviewed remotely by clinical monitors. * Process can be discussed at SIV and at other times if necessary. * Consent process will be checked at telephone monitoring call for sites that require support based on site staff research experience. * If issues are identified with consent process by the trial manager during routine data checks these will be escalated to the lead monitor and/or senior clinical trials monitor.   **Onsite:**   * Onsite monitoring   + All participant consent forms will be checked for existence during monitoring visits.   + For selected participants consent forms will be checked for completion including version and date of consent form, that the participant has signed and dated the form themselves and consent was received by a delegated individual   + For those participants selected for monitoring, medical notes will also be checked to ensure all the correct documentation has been completed and the person taking consent is delegated to do so.   + Confirmation that copies of the PIS/ICF were given to the participant as well filed in the medical notes.   + Process can be reviewed at monitoring visits and in dialogue. | | |
| **Increased level of monitoring**  **Remote:**   * Forms may be reviewed remotely by clinical monitors. * Process can be discussed at SIV and at other times if necessary. * Consent process will be checked at telephone monitoring call for sites that require support based on site staff research experience. * If issues are identified with consent process by the trial manager during routine data checks these will be escalated to the lead monitor and/or senior clinical trials monitor.   **Onsite:**   * Onsite monitoring for all participants   + All participant consent forms will be checked during monitoring visits. Consent forms will be checked for completion including version and date of consent form, that the participant has signed and dated the form themselves and consent was received by a delegated individual   + All participants’ medical notes will also be checked to ensure all the correct documentation has been completed and the person taking consent is delegated to do so.   + Confirmation that copies of the PIS/ICF were given to the participant as well filed in the medical notes.   + Process can be reviewed at monitoring visits and in dialogue. | | |

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| **Study Design and Methods** | | |
| Data QC Checks (✓) | On site | Remote |
| Completion of monitoring activities |  |  |
| Detail activities to be performed (delete/modify as required) | | |
| **Reduced level of monitoring**  **Remote:**   * May be reviewed remotely by clinical monitors. * Issues identified at QC check will be escalated to the lead monitor and/or senior clinical trials monitor. | | |
| **Regular level of monitoring**  **Remote:**   * May be reviewed remotely by clinical monitors.   **Onsite:**   * Onsite monitoring   + Sample of CRFs checked during routine monitoring visits for eligibility, endpoint and safety data accuracy. | | |
| **Increased level of monitoring**  **Remote:**   * May be reviewed remotely by clinical monitors.   **Onsite:**   * Onsite monitoring   Sample of CRFs checked during routine monitoring visits all data points. | | |
| CRF Completion (✓) | On site | Remote |
| Completion of monitoring activities |  |  |
| Detail activities to be performed (delete/modify as required) | | |
| **Reduced level of monitoring**  **Remote:**   * May be checked by the DMC, data monitor or clinical monitor remotely via eCRF if applicable. * Clinical monitors can be alerted of poor completion of data by DMC, data monitor, and study team as well as through running missing data reports. * Completion of eCRF will be checked in accordance with the Data management plan (if applicable) * CRF completion will be checked at telephone monitoring call for sites that require support based on site staff research experience. * Issues identified during missing data checks will be escalated to the lead monitor and/or senior clinical trials monitor * Audit trial for eCRF will be reviewed for consent, eligibility, safety and primary endpoint data. Audit trail review will be carried out in conjunction with both onsite visits and remote review. | | |
| **Regular level of monitoring**  **Remote:**   * May be checked by the DMC, data monitor or clinical monitor remotely via eCRF if applicable. * Clinical monitors can be alerted of poor completion of data by DMC, data monitor, and study team as well as through running missing data reports. * Completion of eCRF will be checked in accordance with the Data management plan (if applicable) * CRF completion will be checked at telephone monitoring call for sites that require support based on site staff research experience. * Issues identified during missing data checks will be escalated to the lead monitor and/or senior clinical trials monitor * Audit trial for eCRF will be reviewed for consent, eligibility, safety and primary endpoint data. Audit trail review will be carried out in conjunction with both onsite visits and remote review.   **Onsite:**   * Onsite monitoring   + Paper CRFs will be checked for completion. | | |
| **Increased level of monitoring**  **Remote:**   * May be checked by the DMC, data monitor or clinical monitor remotely via eCRF if applicable. * Clinical monitors can be alerted of poor completion of data by DMC, data monitor, and study team as well as through running missing data reports. * Completion of eCRF will be checked in accordance with the Data management plan (if applicable) * CRF completion will be checked at telephone monitoring call for sites that require support based on site staff research experience. * Issues identified during missing data checks will be escalated to the lead monitor and/or senior clinical trials monitor * Audit trial for eCRF will be reviewed for consent, eligibility, safety and primary endpoint data. Audit trail review will be carried out in conjunction with both onsite visits and remote review.   **Onsite:**   * Onsite monitoring   + Paper CRFs will be checked for completion. | | |
| Protocol/Regulatory Compliance (✓) | On site | Remote |
| Completion of monitoring activities |  |  |
| Detail activities to be performed (delete/modify as required) | | |
| **Reduced level of monitoring**  **Remote:**   * Deviations will be faxed to or emailed to ACCORD QA at three monthly intervals. * Violations will be faxed to or emailed to ACCORD QA within 3 days. * Study teams will be able to contact clinical monitors via telephone or email during the study to discuss compliance. * Telephone monitoring call after site has randomised first participant will check compliance for sites that require support based on site staff research experience. | | |
| **Regular level of monitoring**  **Remote:**   * Deviations will be faxed to or emailed to ACCORD QA at three monthly intervals. * Violations will be faxed to or emailed to ACCORD QA within 3 days. * Study teams will be able to contact clinical monitors via telephone or email during the study to discuss compliance. * Telephone monitoring call after site has randomised first participant will check compliance for sites that require support based on site staff research experience.   **Onsite:**   * Onsite monitoring   + Confirm or observe compliance with study team.   Deviations and violations logs will be reviewed by monitor during monitoring visit and reconciled with ACCORD records | | |
| **Increased level of monitoring**  **Remote:**   * Deviations will be faxed to or emailed to ACCORD QA at three monthly intervals. * Violations will be faxed to or emailed to ACCORD QA within 3 days. * Study teams will be able to contact clinical monitors via telephone or email during the study to discuss compliance. * Telephone monitoring call after site has randomised first participant will check compliance for sites that require support based on site staff research experience.   **Onsite:**   * Onsite monitoring   + Confirm or observe compliance with study team.   + Deviations and violations logs will be reviewed by monitor during monitoring visit and reconciled with ACCORD records. | | |
| SDV of Outcomes (✓) | On site | Remote |
| Completion of monitoring activities |  |  |
| Detail activities to be performed (delete/modify as required) | | |
| **Reduced level of monitoring**  **Remote:**   * SDV for primary and secondary endpoints will be carried out remotely where possible and necessary by monitors. * Sample will be increased if errors are identified. | | |
| **Regular level of monitoring**  **Remote:**   * SDV for primary and secondary endpoints will be carried out remotely where possible and necessary by monitors.   **Onsite:**   * SDV will be carried out for primary and secondary endpoints. These will be checked for 100% of selected participants where possible. * Sample will be increased if errors are identified. | | |
| **Increased level of monitoring**  **Remote:**   * SDV for primary and secondary endpoints will be carried out remotely where possible and necessary by monitors.   **Onsite:**   * SDV will be carried out for primary and secondary endpoints. These will be checked for 100% of selected participants where possible.   Sample will be increased if errors are identified. | | |

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| **Study Organisation** | | |
| Staff Training (✓) | On site | Remote |
| Completion of monitoring activities |  |  |
| Detail activities to be performed (delete/modify as required) | | |
| **Reduced level of monitoring**  **Remote:**   * Study team will receive training in the sponsor’s SOPs and conducting a study to GCP and study protocol as required. * Access to eCRF will not be given to an individual without prior completion of study specific and Sponsor’s SOP training. | | |
| **Regular level of monitoring**  **Remote:**   * Study team will receive training in the sponsor’s SOPs and conducting a study to GCP and study protocol as required. * Access to eCRF will not be given to an individual without prior completion of study specific and Sponsor’s SOP training.   **Onsite:**   * Onsite monitoring   + Additional training needs will be reviewed during the course of routine monitoring and additional training will be provided to the study team as necessary. | | |
| **Increased level of monitoring**  **Remote:**   * Study team will receive training in the sponsor’s SOPs and conducting a study to GCP and study protocol as required. * Access to eCRF will not be given to an individual without prior completion of study specific and Sponsor’s SOP training.   **Onsite:**   * Onsite monitoring   Additional training needs will be reviewed during the course of routine monitoring and additional training will be provided to the study team as necessary. | | |
| Recruitment Reporting (✓) | On site | Remote |
| Completion of monitoring activities |  |  |
| Detail activities to be performed (delete/modify as required) | | |
| **Reduced level of monitoring**  **Remote:**   * Levels of recruitment discussed between the study team and the sponsor as necessary. | | |
| **Regular level of monitoring**  **Remote:**   * Levels of recruitment discussed between the study team and the sponsor as necessary.   **Onsite:**   * Onsite monitoring   + Screening and pre-screening logs will be checked during monitoring visits.   + Recruitment will be recorded and discussed during any monitoring visits. | | |
| **Increased level of monitoring**  **Remote:**   * Levels of recruitment discussed between the study team and the sponsor as necessary.   **Onsite:**   * Onsite monitoring   + Screening and pre-screening logs will be checked during monitoring visits.   + Recruitment will be recorded and discussed during any monitoring visits. | | |
| Facilities & Resources (✓) | On site | Remote |
| Completion of monitoring activities |  |  |
| Detail activities to be performed (delete/modify as required) | | |
| **Remote monitoring:**   * Issues identified with facilities and resources which cannot be resolved by the trial management team will be escalated to the lead monitor and to the Sponsor representatives where required. | | |
| **Onsite monitoring:**   * Any issues identified during onsite visits will be noted in monitoring report and escalated to Sponsor representatives where resolution by the trial management team is not possible. | | |
| Detail activities to be performed for study samples (delete/modify as required) | | |
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| Records & Delegation (✓) | On site | Remote |
| Completion of monitoring activities |  |  |
| Detail activities to be performed (delete/modify as required) | | |
| **Reduced level of monitoring**  **Remote:**   * Guidance on ISF provided by clinical monitors. * Delegation logs provided by clinical monitors, for completion by the PI. | | |
| **Regular level of monitoring**  **Remote:**   * Guidance on ISF provided by clinical monitors. * Delegation logs provided by clinical monitors, for completion by the PI.   **Onsite:**   * Onsite monitoring   + Study team may be provided with prepared ISF by the clinical monitors/trial management if possible.   + Delegation log checked at monitoring visit along with ISF. | | |
| **Increased level of monitoring:**  **Remote:**   * Guidance on ISF provided by clinical monitors. * Delegation logs provided by clinical monitors, for completion by the PI.   **Onsite:**   * Onsite monitoring   + Study team may be provided with prepared ISF by the clinical monitors/trial management unless otherwise stated in the monitoring plan.   Delegation log checked at monitoring visit along with ISF. | | |

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| **Other Monitoring Tasks** | | |
| Telephone monitoring call (✓) | On site | Remote |
| Completion of monitoring activities |  |  |
| Detail activities to be performed | | |
| During SIV the Clinical Trials Monitor/Trial Manager will assess whether a site requires support based on site staff research experience.  Each site that requires support will receive a telephone call after they randomise their first participant. The call will include checks on:   * Consent process * Eligibility process * Randomisation process * Dose escalation * Data collection   Calls will be performed by Clinical Trials Monitor/Trial management team and recorded on a study specific telephone monitoring report. A copy of this report will be sent to the lead monitor for review. | | |
| (for completion when SDV planning performed) | On site | Remote |
| Completion of monitoring activities |  |  |
| Detail activities to be performed | | |
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| (for completion when SDV planning performed) | On site | Remote |
| Completion of monitoring activities |  |  |
| Detail activities to be performed | | |
|  | | |
| (for completion when SDV planning performed) | On site | Remote |
| Completion of monitoring activities |  |  |
| Detail activities to be performed | | |
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| **Documentation of Remote Monitoring** |
| If remote monitoring methods will be utilised, briefly describe how the completion of remote monitoring tasks will be recorded and the timeline for documenting and reporting findings. Also document where the evidence for completion of remote monitoring will be filed. |
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| CRF Source Data Capture |
| Where source data will be captured directly on the CRF (pCRF or eCRF), where will this be documented? |
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| **Plan Signatures** | | | |
| **SDV Plan Completion** | | | |
| Plan completed by |  | Role |  |
| Plan completed date |  | Date plan sent for review |  |
| Signature |  | Date |  |
| **SDV Plan Review** | | | |
| Plan Reviewed by |  | Role |  |
| Date plan received for review |  | Date review completed |  |
| Signature |  | Date |  |