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| **Study Details** | | | |
| Study Title |  | | |
| Site |  | REC Reference |  |
| Trust/ Health board |  | Lothian R&D Reference |  |
| PI Name |  | | |
| PI Contact Details |  | | |

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| **Monitor Verifications** | | | | |
| (✓) | Confirmed | Checked Remotely | N/A | Comments |
| Monitoring plan in place and signed |  |  |  |  |
| Facilitation checklist complete and signed (as per FA001) |  |  |  |  |
| Data capture detailed and approved by monitor and CRF tracker in place |  |  |  |  |
| Monitor access to database/eCRF confirmed |  |  |  |  |
| Database checklist applied and database accepted (only applicable if database includes electronic systems required for commencement of study) |  |  |  |  |
| Data Management Plan in place |  |  |  |  |
| Randomisation procedure in place and compliant with protocol |  |  |  |  |
| Trial registered on publicly accessible database |  |  |  |  |

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| **Site Level Verifications** | | | | |
| (✓) | Confirmed | Checked Remotely | N/A | Comments |
| Local approval in place and all conditions met |  |  |  |  |
| Latest version of protocol signed by all signatories |  |  |  |  |
| Correct version/date of study documents present  (PIS/Consent Form/adverts/etc) |  |  |  |  |
| PI CV in TMF and ISF |  |  |  |  |
| PI GCP evidence in TMF and ISF |  |  |  |  |
| Delegation log in place |  |  |  |  |
| Screening log in place |  |  |  |  |
| Patient ID log in place |  |  |  |  |
| Source Data Plan (CR004-T01) complete |  |  |  |  |
| SIV process complete |  |  |  |  |
| Labels provided for clinical trial samples |  |  |  |  |
| Unblinding procedure in place compliant with protocol and tested by site |  |  |  |  |
| Agreement with Investigator in TMF and ISF (site agreement or equivalent) |  |  |  |  |
| Adequate resources in place to begin recruitment |  |  |  |  |
| **CTIMP Studies** | | | | |
| (✓) | Confirmed | Checked Remotely | N/A | Comments |
| Regulatory Greenlight Checklist (CM001 T03) completed and filed in TMF/Sponsor file |  |  |  |  |
| Investigator’s Brochure or SmPC in place for all IMPs & nIMPs |  |  |  |  |
| Shipping records verified |  |  |  |  |
| IMP in place |  |  |  |  |
| Complete only if CM001 T03 N/A:   * Accountability approved by Sponsor and in place at site (GS010-T02) |  |  |  |  |
| Complete only if CM001 T03 N/A:  Prescription approved by Sponsor and in place at site (GS010-T03) |  |  |  |  |
| Complete only if CM001 T03 N/A:  Pharmacy manual/IMP instructions approved by Sponsor (GS010-T04) |  |  |  |  |
| Complete only if CM001 T03 N/A:   * Pharmacy ready and approved to proceed |  |  |  |  |
| Complete only if CM001 T03 N/A:   * Labels accurate and consistent with MHRA approval |  |  |  |  |
| **Medical Device Studies** | | | | |
| (✓) | Confirmed | Checked Remotely | N/A | Comments |
| Regulatory Greenlight Checklist (CM001 T03) completed and filed in TMF/Sponsor file |  |  |  |  |
| Investigator’s Brochure in place |  |  |  |  |
| Shipping records verified |  |  |  |  |
| Signed Manufacturers statement of conformity in place |  |  |  |  |

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| **Authorised Documents** | | |
| Document Type | Version | Date |
| Protocol |  |  |
| Patient Information Sheet |  |  |
| Informed Consent Form |  |  |
| GP Letter |  |  |
| Letter of Invitation to Participants |  |  |
| Reference Safety Information |  |  |
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| **Declaration** |
| *This document confirms the authorisation from the study sponsor to open the specified trial site for recruitment. This authorisation permits the research team to proceed with all study activities/screening only/dosing (delete as appropriate) at this trial site.* |

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| **Report Signatures** | | | |
| **Authorisation Completion** | | | |
| Report completed by |  | Role |  |
| Report completed date |  | Date sent for review |  |
| Signature |  | Date |  |
| **Authorisation Review** | | | |
| Report Reviewed by |  | Role |  |
| Report Receipt date |  | Date review completed |  |
| Signature |  | Date |  |