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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Sponsor Ref** |  | **EudraCT Ref** | |  | | **REC Ref** | |  | **R&D** |  |
| **Protocol Title** |  | | | | | | | | | |
| **Chief Investigator** |  | | | | | | | | | |
| **Trial Pharmacist** |  | | | **Address** | |  | | | | |
| **Site Name** |  | | | **Site No.** | |  | | | | |
| **IMP** |  | | | | | | | | | |
| **Document** | | | **Version** | | **Date** | | **Comments** | | | |
| Protocol | | |  | |  | |  | | | |
| IB/SmPc | | |  | |  | |  | | | |
| MHRA Approval | | |  | |  | |  | | | |
| REC favourable opinion | | |  | |  | |  | | | |
| R&D Permission | | |  | |  | |  | | | |
| Date of Co-sponsorship agreement | | |  | |  | |  | | | |
| Confirmation of QP release (Active + Placebo) | | |  | |  | |  | | | |
| Current Clinical Trials Insurance UoA/ CNORIS NHS-G | | |  | |  | |  | | | |
| Confirm all conditions of approvals have been met | | |  | |  | |  | | | |
| Technical agreements in place | | |  | |  | |  | | | |
| Laboratory File/Folder in place | | |  | |  | |  | | | |
| Authorised Prescribers’ Signature Log | | |  | |  | |  | | | |
| Unblinding documentation in Pharmacy | | |  | |  | |  | | | |

The CTIMP is approved to commence recruitment and for the dispensing of IMP/Placebo only when this document has been signed by both the NHS-Grampian CTP and the NHSG/University RGM

**Signed on behalf of CTP**: Signature: Date:

Job Title: Print Name:

**Signed on behalf of the Co-Sponsor:** Signature: Date:

Job Title: Print Name: