|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Study Name: |  | | | | | |
| Sponsor code: |  | Chief Investigator: |  | | | |
| Location of TMF: |  | Sponsor File: | Yes |  | No |  |

**This checklist should be made trial specific at the beginning of the trial and used as a tool to mark the location of each essential document. Some documents may not be applicable to a trial and should be marked as such below. Comments can be recorded in the Comment column as required.**

The document checklist should be updated as documents are added to the file and the version/ date of the document added when appropriate. The document checklist can also be used to document a review of the file by completing the review section below. A sponsor file will exist for trials where the TMF is delegated to the trial team. Documents which should not be held in the sponsor file, trial master file (TMF) or investigator site file (ISF) are greyed out. Some documents may be held electronically, only on electronic media e.g. CD or memory stick within the paper file. The location of electronic documents must be file noted within the paper file.

Please complete:

|  |
| --- |
| Update of file and checklist only □ Full file review □ *If a full file review was conducted please complete review section at end of index* |

| Section | Sub-Section | Document | Version/ date | Location (✓) | | | | | Comment |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sponsor file | TMF | ISF | Electronic only | N/A |  |
| 1. Study Documents | 1.1 Current | Protocol (*fully signed)* |  |  |  |  |  |  |  |
| PIS |  |  |  |  |  |  |  |
| Consent |  |  |  |  |  |  |  |
| GP letter |  |  |  |  |  |  |  |
| Other study specific docs (list) |  |  |  |  |  |  |  |
| 1.2 Superseded | Protocol (*fully signed)* |  |  |  |  |  |  |  |
| PIS |  |  |  |  |  |  |  |
| Consent |  |  |  |  |  |  |  |
| GP letter |  |  |  |  |  |  |  |
| Other study specific docs (list) |  |  |  |  |  |  |  |
| 1.3 | Correspondence |  |  |  |  |  |  |  |
| 2. Approvals | 2.0 Combined Review *(delete if not applicable to study)* | Combined review approvals |  |  |  |  |  |  |  |
| R&D approvals/Capacity and Capability |  | Lothian only |  |  |  |  |  |
| Cover letter *(or equivalent listing versions of documents submitted)* |  |  |  |  |  |  |  |
| Correspondence (*incl. acknowledgement of submission, grounds for non-acceptance and requests for further info if applicable. Must include list of REC members. Make list study specific, full documentation required in TMF, ensure it is clear what will be located in ISF)* |  |  |  |  |  |  |  |
| Combined review submission (*incl. the Medicines Information, Ethics and Project Study Information documents generated by the CR system, Outline OID, SoECAT. Make list study specific, full documentation required in TMF, ensure it is clear what will be located in ISF)* |  |  |  |  |  |  |  |
| Submitted study documents |  |  |  |  |  |  |  |
| 2.1 Ethics *(delete if combined review)* | Approvals *(Final favourable opinion)* |  |  |  |  |  |  |  |
| Cover letter *(or equivalent which lists document versions submitted)* |  |  |  |  |  |  |  |
| Correspondence  *(may incl. acknowledgement of submission, request for further information, response to REC. Must include list of REC members. Make list study specific, full documentation required in TMF, ensure it is clear what will be located in ISF )* |  |  |  |  |  |  |  |
| IRAS form |  |  |  |  |  |  |  |
| Submitted documents |  |  |  |  |  |  |  |
| 2.2 Regulatory *(delete if combined review)* | Approvals |  |  |  |  |  |  |  |
| Cover letter *(or equivalent which lists document versions submitted)* |  |  |  |  |  |  |  |
| Correspondence *(incl. acknowledgement of application, grounds for non-acceptance, response to MHRA. Make list study specific. Full documentation required in TMF, ensure it is clear what will be located in ISF )* |  |  |  |  |  |  |  |
| CTA application |  |  |  |  |  |  |  |
| Submitted documents |  |  |  |  |  |  |  |
| 2.3 R&D *(delete if combined review)* | Approvals / Capacity and Capability |  | Lothian only |  |  |  |  |  |
| Other approvals (*As applicable, e.g. Phase I Committee, ATIMP Committee)* |  |  |  |  |  |  |  |
| Cover letter *(or equivalent which lists document versions submitted)* |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| IRAS form |  |  |  |  |  |  |  |
| SSI form / OID |  | Lothian only |  |  |  |  |  |
| Submitted documents |  |  |  |  |  |  |  |
| 2.4 Amendments | Amendment log *(if multi-site)* |  |  |  |  |  |  |  |
| Combined Review – Substantial Amendment *(delete if not applicable to study)*  NUMBER:  01  DATE:  *(approvals required will depend on the amendment, please make amendment specific)* | Combined review approvals |  |  |  |  |  |  |  |
| R&D approvals/Capacity and Capability |  | Lothian only |  |  |  |  |  |
| HRA/NRSPCC acknowledgement emails |  |  |  |  |  |  |  |
| Amendment tool |  |  |  |  |  |  |  |
| Cover letter *(or equivalent listing versions of documents submitted)* |  |  |  |  |  |  |  |
| Combined review submission (*make study specific, full documentation required in the TMF, ensure it is clear what will be located in the ISF)* |  |  |  |  |  |  |  |
| Submitted study documents (*tracked changes if applicable)* |  |  |  |  |  |  |  |
| Sponsor classification email |  |  |  |  |  |  |  |
| Substantial amendment checklist |  |  |  |  |  |  |  |
| Sponsor implementation email |  |  |  |  |  |  |  |
| Site implementation email |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| Substantial Amendment *(delete if not applicable to study)*  NUMBER: 01  DATE:  *(approvals required will depend on the amendment, please make amendment specific)* | Ethics approval |  |  |  |  |  |  |  |
| Regulatory approval |  |  |  |  |  |  |  |
| R&D approval/Capacity and capability |  | Lothian only |  |  |  |  |  |
| HRA/NRSPCC acknowledgement emails |  |  |  |  |  |  |  |
| Amendment tool |  |  |  |  |  |  |  |
| Cover letter *(or equivalent which lists document versions submitted)* |  |  |  |  |  |  |  |
| Submitted documents (*tracked changes if applicable)* |  |  |  |  |  |  |  |
| Sponsor classification email |  |  |  |  |  |  |  |
| Substantial amendment checklist |  |  |  |  |  |  |  |
| Sponsor implementation email |  |  |  |  |  |  |  |
| Site level implementation email |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| Combined Review – Non Substantial Amendment *(delete if not applicable to study)*  NUMBER: 01  DATE:  *(approvals required will depend on the amendment, please make amendment specific)* | R&D approvals/Capacity and Capability *(if applicable – e.g. Category B)* |  | Lothian only |  |  |  |  |  |
| R&D acknowledgement (*if applicable –e.g. Category C*) |  | Lothian only |  |  |  |  |  |
| HRA/NRSPCC acknowledgement emails |  |  |  |  |  |  |  |
| Amendment tool |  |  |  |  |  |  |  |
| Sponsor classification and implementation email |  |  |  |  |  |  |  |
| Site level implementation email |  |  |  |  |  |  |  |
| Submitted documents *(tracked changes if applicable)* |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| Non Substantial Amendment *(delete if not applicable to study)*  NUMBER: 01  DATE:  *(approvals required will depend on the amendment, please make amendment specific)* | R&D approval/Capacity and capability *(if applicable – e.g. Category B)* |  | Lothian only |  |  |  |  |  |
| R&D acknowledgement (*if applicable –e.g. Category C*) |  | Lothian only |  |  |  |  |  |
| HRA/NRSPCC acknowledgement emails |  |  |  |  |  |  |  |
| Amendment tool |  |  |  |  |  |  |  |
| Sponsor classification and implementation email |  |  |  |  |  |  |  |
| Site level implementation email |  |  |  |  |  |  |  |
| Submitted documents *(tracked changes if applicable)* |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| 2.5 Progress Reports | APR |  |  |  |  |  |  |  |
| Evidence of submission |  |  |  |  |  |  |  |
| Acknowledgement |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| 2.6 End of Trial | End of study report |  |  |  |  |  |  |  |
| Combined Review – End of Trial Reporting (*delete if not applicable to study)* | Confirmation of end of trial reporting submission |  |  |  |  |  |  |  |
| End of Trial Reporting (*delete if not applicable to study* | Declaration of End of Trial form |  |  |  |  |  |  |  |
| Notification to REC and acknowledgement |  |  |  |  |  |  |  |
| Notification to regulatory body and acknowledgement |  |  |  |  |  |  |  |
| Notification to R&D and acknowledgement |  | Lothian Only |  |  |  |  |  |
| 3. Contracts and Funding | 3.1 Sponsorship and Insurance | Co-sponsorship agreement |  |  |  | Lothian only |  |  |  |
| Facilitation checklist |  |  |  |  |  |  |  |
| Sponsor Regulatory Checks Complete email |  |  |  |  |  |  |  |
| Insurance letter/statement |  |  |  |  |  |  |  |
| * 1. Agreements | Technical agreements |  |  |  |  |  |  |  |
| Site agreements |  |  |  |  |  |  |  |
| Other (list) |  |  |  |  |  |  |  |
| * 1. Funding | Funding application |  |  |  |  |  |  |  |
| Award letter |  |  |  |  |  |  |  |
|  | Correspondence |  |  |  |  |  |  |  |
| 4. Participant Documents | 4.1 | Subject log |  |  |  |  |  |  |  |
| 4.2 | Consent forms |  |  |  |  |  |  |  |
| 5. Safety | 5.1 Unblinding | Unblinding procedure |  |  |  |  |  |  |  |
| Documentation of Broken Blinds |  |  |  |  |  |  |  |
| 5.2 Safety reporting | PhV work instructions |  |  |  |  |  |  |  |
| Blank safety reporting forms |  |  |  |  |  |  |  |
| Completed SAE/SAR/SUSAR/AE reports |  |  |  |  |  |  |  |
| SAE summary sheet *(filed for each SAE, produced by PV team, filed by sponsor only)* |  |  |  |  |  |  |  |
| Correspondence (*incl Sponsor acknowledgement of receipt for SAEs)* |  |  |  |  |  |  |  |
| Evidence of onwards reporting |  |  |  |  |  |  |  |
| Line listings |  |  |  |  |  |  |  |
| 5.3 DSUR | DSUR |  |  |  |  |  |  |  |
| Evidence of submission |  |  |  |  |  |  |  |
| Acknowledgement |  |  |  |  |  |  |  |
| 5.4 Protocol Violations | Violation reports |  |  |  |  |  |  |  |
| Suspected serious breach reports |  |  |  |  |  |  |  |
| Correspondence (*incl. Sponsor acknowledgement of receipt)* |  |  |  |  |  |  |  |
| 5.5 Protocol Deviations | Deviation logs |  |  |  |  |  |  |  |
| Correspondence (*incl. Sponsor acknowledgement of receipt)* |  |  |  |  |  |  |  |
| 6. Research Team | 6.1 | Delegation log |  |  |  |  |  |  |  |
| 6.2 | Chief Investigator CV  Chief Investigator GCP certificate |  |  |  |  |  |  |  |
| PI and Site Team CVs  PI and Site Team GCP certificates |  |  |  |  |  |  |  |
| 6.3 | Other relevant training (*training logs)* |  |  |  |  |  |  |  |
| 6.4 | Site contact list *(if multi site)* |  |  |  |  |  |  |  |
| 7. Monitoring and Audit | 7.1 Risk Assessments | ACCORD combined RA |  |  |  |  |  |  |  |
| Superseded combined RAs |  |  |  |  |  |  |  |
| Other risk assessment (list) |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| 7.2 Monitoring Plan | Monitoring and SDV plan |  |  |  |  |  |  |  |
| Superseded monitoring and SDV plans |  |  |  |  |  |  |  |
| Source data plan |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| 7.3 Monitoring Reports | Feasibility form |  |  |  |  |  |  |  |
| Site risk indicator tool |  |  |  |  |  |  |  |
| SIV (report and letter) |  |  |  |  |  |  |  |
| Regulatory green light |  |  |  |  |  |  |  |
| SATO |  |  |  |  |  |  |  |
| Monitoring visit report |  |  |  |  |  |  |  |
| Monitoring visit follow up letter |  |  |  |  |  |  |  |
| Action logs |  |  |  |  |  |  |  |
| Monitoring visit correspondence |  |  |  |  |  |  |  |
| Site level close out checklist |  |  |  |  |  |  |  |
| Close out visit report |  |  |  |  |  |  |  |
| Close out visit follow up letter |  |  |  |  |  |  |  |
| Close out visit action log (*signed*) |  |  |  |  |  |  |  |
| Final close out letter |  |  |  |  |  |  |  |
| Study level close out checklist |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| Contact reports |  |  |  |  |  |  |  |
| Documentation of recruitment checks |  |  |  |  |  |  |  |
| 7.4 Audit | Observations |  |  |  |  |  |  |  |
| Certificate |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| 7.5 Vendors | Vendor assessment and approval |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| 8. Pharmacy and Labs | 8.1 IMP | Current IB/SmPC |  |  |  |  |  |  |  |
| Superseded IBs/SmPCs |  |  |  |  |  |  |  |
| SmPC/IB updates |  |  |  |  |  |  |  |
| Correspondence (*Incl. drug alerts if applicable)* |  |  |  |  |  |  |  |
| Product Specification File | *For trials where ISG manufacture IMP only: This file will be held by ISG for the duration of the trial. To be added to the ACCORD held TMF/SF at end of trial for archiving.* | | | | | | |
| 8.2 Pharmacy | Sample labels |  |  |  |  |  |  |  |
| Accountability log templates |  |  |  |  |  |  |  |
| Accountability logs (completed) |  |  |  |  |  |  |  |
| Sponsor Accountability log review |  |  |  |  |  |  |  |
| Prescription templates |  |  |  |  |  |  |  |
| Prescriptions (completed) |  |  |  |  |  |  |  |
| Sponsor Prescription review |  |  |  |  |  |  |  |
| QP release certificates |  |  |  |  |  |  |  |
| Pharmacy/IMP handling instructions |  |  |  |  |  |  |  |
| Sponsor review of Pharmacy/IMP instructions |  |  |  |  |  |  |  |
| Site specific external IMP storage risk assessments |  |  |  |  |  |  |  |
| Temperature monitoring calibration certificates |  |  |  |  |  |  |  |
| Temperature logs |  |  |  |  |  |  |  |
| Drug delivery/return records |  |  |  |  |  |  |  |
| Destruction records |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| 8.3 Labs | Lab accreditations |  |  |  |  |  |  |  |
| Reference ranges |  |  |  |  |  |  |  |
| Laboratory/sample handling instructions |  |  |  |  |  |  |  |
| Sample accountability logs |  |  |  |  |  |  |  |
| Sample storage logs |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| 9. Data management | 9.1 CRFs  *(requirements for paper and eCRF will differ, please make study specific)* | Blank copy of current CRF *(pCRF)* |  |  |  |  |  |  |  |
| Superseded versions of CRF *(pCRF)* |  |  |  |  |  |  |  |
| Completed CRFs *(pCRFs or eCRF - consider at end of trial)* |  |  |  |  |  |  |  |
| CRF tracker |  |  |  | pCRF only |  |  |  |
| CRF review |  |  |  |  |  |  |  |
| Blank copy of current source data worksheet |  |  |  |  |  |  |  |
| Superseded source data worksheet |  |  |  |  |  |  |  |
| Data Management Plan |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| 9.2 Computer Systems | Validation checklist |  |  |  |  |  |  |  |
| Validation documents |  |  |  |  |  |  |  |
| System release history |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| 9.3 Statistics | Master randomisation list *(consider blinding, may be added at end of trial)* |  |  |  |  |  |  |  |
| Statistical Analysis Plan |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| 10. Meeting Minutes | 10.1 DMC | DMC charter |  |  |  |  |  |  |  |
| DMC minutes |  |  |  |  |  |  |  |
| DMC report |  |  |  |  |  |  |  |
| Completed dose escalation form |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| 10.2 TSC | TSC charter |  |  |  |  |  |  |  |
| TSC minutes |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| 10.3 TMG | TMG minutes |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| 10.4 Other (list) | Minutes |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Full file review | | | |
| Review of | Sponsor File □ | TMF □ | ISF □ |
| Review completed by |  | | |
| Date of review | DD MMM YYYY | | |
| List of documents required |  | | |