|  |  | Sections in grey text are not applicable for this trial and corresponding documents will thus not be filed in this binder. | If filed at other location, state location |
| --- | --- | --- | --- |
|  | **A** | **General Trial Information** | |
|  | 1 | Contact information (Sponsor/Coordinator) |  |
|  | 2 | Flowchart, list of in and exclusion criteria, synopsis |  |
|  | 3 | Guidelines for local procedures (nursing guidelines, studymanual etc.) |  |
|  | 4 | FAQ |  |
|  | 5 | Trial checklist (inquiry, feasibility, activation, close-out etc.) |  |
|  | 6 | Newsletters |  |
|  |  | Correspondence |  |
|  |  |  |  |
|  | **B** | **Site Staff** | |
|  | 1 | Contact information (local) |  |
|  | 2 | Signature and delegation of responsibilities log (signed original) |  |
|  | 3 | Meetings and minutes |  |
|  | 4 | Training records (incl investigator meetings) |  |
|  | 5 | CV local (sub-) investigator (signed and dated) |  |
|  | 6 | CV independent physician (signed and dated) |  |
|  | 7 | Other applicable CV’s |  |
|  |  | Correspondence |  |
|  |  |  |  |
|  | **C** | **Protocol** | |
|  | 1 | Current protocol and amendments |  |
|  |  | 1.1 Current signed protocol and amendments |  |
|  |  | 1.2 Summary of changes |  |
|  | 2 | Previous protocol and amendments |  |
|  |  | 2.1 Previous signed protocol and amendments |  |
|  |  | 2.2 Summary of changes |  |
|  | 3 | Country-specific addendum (international trials) |  |
|  |  | Correspondence |  |
|  |  |  |  |
|  | **D** | **Trial Subject Related Documents** | |
|  | 1 | Subject identification code list + screening/enrollment log templates |  |
|  | 2 | PIF/ICF templates (chronological order) |  |
|  | 3 | Questionnaire templates (chronological order) |  |
|  | 4 | Diary templates (chronological order) |  |
|  | 5 | Subject recruitment |  |
|  | 6 | Other trial subject related documents |  |
|  |  | Correspondence |  |
|  |  |  |  |
|  | **E** | **Trial Subject Related Information and Identification** | |
|  | 1 | Subject identification code list + screening/enrollment log |  |
|  | 2 | Trial subject information (filed per subject) |  |
|  |  | 2.1 Signed ICF (signed and dated original) |  |
|  |  | 2.2 Registration and randomization result |  |
|  |  | 2.3 Completed questionnaires |  |
|  |  | 2.4 Completed diaries |  |
|  |  | 2.5 Other source documentation |  |
|  |  | 2.6 Completed SAE forms |  |
|  |  | 2.7 Completed CRF |  |
|  |  | 2.8 Completed statement of expenses forms (trial subjects) |  |
|  |  | 2.9 Subject specific correspondence |  |
|  |  | Correspondence |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  | **F** | **Contracts and Agreements** | |
|  | 1 | Local research declaration (onderzoeksverklaring) |  |
|  | 2 | Protocol signature page local investigator (signed original) |  |
|  | 3 | Clinical trial agreement |  |
|  | 4 | Statement of expenses forms |  |
|  | 5 | Other agreements (financial disclosure, confidentiality etc.) |  |
|  |  | Correspondence |  |
|  |  |  |  |
|  | **G** | **Regulatory Documents** | |
|  | 1 | Ethics committee (EC) |  |
|  |  | 1.1. Approvals and EC composition |  |
|  |  | 1.2 Correspondence |  |
|  | 2 | Competent authority (CA) |  |
|  |  | 2.1 Approvals and notifications |  |
|  |  | 2.2. Correspondence |  |
|  | 3 | Board of directors |  |
|  |  | 3.1 Approvals and notifications |  |
|  |  | 3.2 Correspondence |  |
|  | 4 | Other applicable authorities |  |
|  |  | 4.1 Approvals and notifications |  |
|  |  | 4.2 Correspondence |  |
|  | 5 | Trial reports |  |
|  |  | 5.1 (Annual) reports |  |
|  |  | 5.2 End of trial report |  |
|  |  | 5.3 Clinical study report |  |
|  | 6 | Other |  |
|  |  |  |  |
|  |  |  |  |
|  | **H** | **Trial Medication** | |
|  | 1 | Product information: Investigator’s Brochure, SmPC |  |
|  | 2 | Quality assurance |  |
|  | 3 | Instructions for trial medication |  |
|  | 4 | Orders |  |
|  | 5 | Accountability |  |
|  | 6 | Receipt/shipping |  |
|  | 7 | Destruction/return |  |
|  | 8 | Incident report |  |
|  | 9 | Other applicable documents |  |
|  |  | Correspondence |  |
|  |  |  |  |
|  | **I** | **Central Laboratory and Central Review** |  |
|  | 1 | Local procedures for central assessment |  |
|  | 2 | Samples and shipping information |  |
|  |  | Correspondence |  |
|  |  |  |  |
|  | **J** | **Local Laboratory, Assessments and Samples** | |
|  | 1 | Reference values |  |
|  | 2 | Certification/accreditation |  |
|  | 3 | Samples and storage information |  |
|  |  | Correspondence |  |
|  |  |  |  |
|  | **K** | **CRF, Database and Datamanagement** | |
|  | 1 | Sample CRF (chronological order) |  |
|  | 2 | CRF guidelines (chronological order) |  |
|  | 3 | Randomization/registration information |  |
|  |  | Correspondence |  |
|  | **L** | **Safety** | |
|  | 1 | Blinding and unblinding information |  |
|  | 2 | Safety procedures (SAE reporting instructions) |  |
|  | 3 | SAE/SUSAR |  |
|  |  | 3.1 SAE form template and instructions (chronological order) |  |
|  |  | 3.2 SUSAR reports |  |
|  |  | 3.3 SAE/SUSAR line listings |  |
|  |  | 3.4 Safety letters |  |
|  |  | Correspondence |  |
|  |  |  |  |
|  | **M** | **Monitoring** | |
|  | 1 | Monitor visit log |  |
|  | 2 | Initiation/activation (attendance logs, activation notification etc.) |  |
|  | 3 | Follow up letters and/or visit reports |  |
|  | 4 | Other monitoring documents |  |
|  |  | Correspondence |  |
|  |  |  |  |
|  | **N** | **Insurance** | |
|  | 1 | Insurance certificates |  |
|  |  | Correspondence |  |
|  |  |  |  |
|  | **O** | **Audits and Inspections** | |
|  | 1 | Audit documents |  |
|  | 2 | Inspections documents |  |
|  |  | Correspondence |  |
|  |  |  |  |
|  | **Z** | **General Correspondence and other relevant documentation** | |