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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **A. General Trial Information** |  | **A. 1** Contact information (sponsor/coordinator) |  | **A. 2**Flowchart, list of in and exclusion criteria, synopsis |  | **A. 3**Guidelines for local procedures |  | **A. 4**FAQ |
| **A. 5**Trial checklists |  | **A. 6**Newsletters |  | Correspondence |  | **B. Site Staff** |  | **B. 1**Contact information (Local) |
| **B. 2**Signature and delegation of responsibilities log |  | **B. 3**Meetings and minutes |  | **B. 4**Training records |  | **B. 5**CV Local (sub-) investigator |  | **B. 6**CV Independent physician |
| **B. 7**Other applicable CV’s |  | Correspondence |  | **C. Protocol** |  | **C. 1.1****Current** Signed protocol and amendments |  | **C. 1.2****Current** Summary of changes |
| **C. 2.1****Previous** Signed protocol and amendments |  | **C. 2.2****Previous** Summary of changes |  | **C. 3** Country-specific addendum |  | Correspondence |  | **D. Trial Subject Related Documents** |
| **D. 1**Subject ID code list + screening/enrollment log templates |  | **D. 2** PIF/ICF templates *(chronological order)* |  | **D. 3**Questionnaire templates*(chronological order)* |  | **D. 4**Diary templates*(chronological order)* |  | **D. 5**Subject recruitment |
| **D. 6**Other trial subject related documents |  | Correspondence |  | **E. Trial Subject Information and Identification** |  | **E. 1**Subject identification code list + screening/enrollment log  |  | **E. 2.1****Trial Subject Information:***Signed ICF* |
| **E. 2.2****Trial Subject Information:***Registration and randomization result* |  | **E. 2.3****Trial Subject Information:***Completed questionnaires* |  | **E. 2.4****Trial Subject Information:***Completed diaries* |  | **E. 2.5****Trial Subject Information:***Other source documentation* |  | **E. 2.6****Trial Subject Information:***Completed SAE forms*  |
| **E. 2.7****Trial Subject Information:***Completed CRF*  |  | **E. 2.8****Trial Subject Information:***Completed statement of expenses forms* |  | **E. 2.9****Trial Subject Information:***Subject specific correspondence* |  | Correspondence |  | **F. Contracts and Agreements** |
| **F. 1**Local research declaration |  | **F. 2**Protocol signature page local investigator |  | **F. 3**Clinical trial agreement |  | **F. 4**Statement of expenses forms |  | **F. 5**Other agreements |
| Correspondence |  | **G. Regulatory Documents** |  | **G. 1.1*****Ehics Committee:*** *Approvals and EC composition* |  | **G. 1.2*****Ethics Committee:*** *Correspondence* |  | **G. 2.1*****Competent Authority:*** *Approvals and notifications* |
| **G. 2.2*****Competent Authority:*** *Correspondence* |  | **G. 3.1****Board of Directors:** *Approvals and notifications* |  | **G. 3.2****Board of Directors:** *Correspondence* |  | **G. 4.1****Other Applicable Authorities:** *Approvals and notifications* |  | **G. 4.2****Other Applicable Authorities:** *Correspondence* |
| **G. 5.1.****Trial Reports:***(Annual) reports* |  | **G. 5.2****Trial Reports:***End of trial report* |  | **G. 5.3****Trial Reports:***Clinical study report* |  | **G. 6**Other |  | **H. Trial Medication** |
| **H. 1**Product information |  | **H. 2**Quality assurance |  | **H. 3**Instructions for trial medication |  | **H. 4**Orders |  | **H. 5**Accountability |
| **H. 6**Receipt/shipping |  | **H. 7**Destruction/return |  | **H. 8**Incident report |  | **H. 9**Other applicable documents |  | Correspondence |
| **I. Central Laboratory and Central Review** |  | **I. 1**Local procedures for central assessment |  | **I. 2** Samples and shipping information |  | Correspondence |  | **J. Local Laboratory, Assessments and Samples** |
| **J. 1**Reference values |  | **J. 2**Certification/ accreditation |  | **J. 3**Samples and storage information |  | Correspondence |  | **K. CRF, Database and Datamanagement** |
| **K. 1**Sample CRF*(chronological order)* |  | **K. 2**CRF guidelines*(chronological order)* |  | **K. 3** Randomization / registration information |  | Correspondence |  | **L. Safety** |
| **L. 1**Blinding and unblinding information |  | **L. 2**Safety procedures |  | **L. 3.1****SAE/SUSAR:***SAE form template and instructions* |  | **L. 3.2****SAE/SUSAR:***SUSAR reports* |  | **L. 3.3****SAE/SUSAR:***SAE/SUSAR line listings* |
| **L. 3.4****SAE/SUSAR:***Safety letters* |  | Correspondence |  | **M. Monitoring** |  | **M. 1**Monitor visit log |  | **M. 2** Initiation / activation |
| **M. 3**Follow up letters and/or visit reports |  | **M. 4.** Other monitoring documents |  | Correspondence |  | **N. Insurance** |  | **N. 1**Insurance Certificates |
| Correspondence |  | **O. Audits and Inspections** |  | **O. 1**Audit documents |  | **O. 2**Inspection documents |  | Correspondence |
| **Z. General Correspondence and Other Relevant Documentation** |  |  |  |  |  |  |  |  |