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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** |  |  |  |  |  |  |  |  |