Annexure 9

Essential Documents for the Conduct of a Clinical Trial- Checklist

Good clinical practices- Central Drugs Standard Control Organisation (CDSCO)

Before the clinical phase of the study commences

During this planning stage the following documents should be generated and should be on file before the trial formally starts

1. **Investigator's brochure** ☐
   (To document that relevant and current scientificinformation about the investigational product has been provided)
2. **Informed consent form (including applicable translations)** ☐
   (To document the informed consent .Appropriate information (content and wording), to support their ability to give fully informed consent)
3. **Insurance statement** ☐
   (To document that compensation to subject(s) for trial-related injury will be available)
4. **Dated, documented approval -independent ethics committee (IEC)** ☐
   (To document that the trial has been subject to IEC review and given approval)
5. **Curriculum vitae and/or other relevant documents evidencing qualifications of Investigator(s)** ☐
   (To document qualifications and eligibility to conduct trial and/or provide medical supervision of subjects)
6. **Normal value(s) / range(s) for medical / laboratory / technical procedure(s) and/or test(s) included in the protocol** ☐
   (To document normal values and/or ranges of the tests)
7. **Sample of label(s) attached to investigational product container(s)** ☐
   (To document compliance with applicable labelling regulations and appropriateness of instructions provided to the subjects)
8. **Handling instructions investigational product(s) &trial-related materials** ☐
   (To document instructions needed to ensure proper storage, packaging, dispensing and disposition)
9. **Shipping records for investigational and trial-related materialsand Certificate(s) of analysis of investigational product(s) shipped** ☐
   (Allows tracking of product batch, review of shipping conditions, & accountability)
10. **Master randomisation list & Decoding procedures (blinded trials)** ☐
    (To document method for randomisation of trial population, to document how, in case of an emergency, identity of blindedinvestigational product can be revealed without breaking the blind for the remaining subject's treatment)

During the Clinical Conduct of the Trial

In addition to the above documents, the following should be added during the trial as evidence that all new relevant information is documented as it becomes available

11. **Investigator's brochure updates*** ☐
12. **Informed consent form*** ☐
13. **Dated, documented approval -independent ethics committee (IEC)*** ☐
14. **Curriculum vitae and/or other relevant documents evidencing qualifications of any new Investigator(s)*** ☐
15. **Normal value(s) / range(s) for medical / laboratory / technical procedure(s) and/or test(s) included in the protocol*** ☐

    (*any new information/ updates, should be added to the available information)

16. **Medical / laboratory / technical procedures / tests– certification/ accreditation/ established quality control Sample of label(s) attached to investigational product container(s)** ☐
    (To document that tests remain adequate throughout the trial period)
17. **Documentation of investigational product(s) and trial-related material shipment** ☐
    (Allows tracking of product batch, review of shipping conditions, & accountability)
18. **Monitoring visit reports-**(To document site visits by, and findings of, the monitor) ☐
19. **Relevant communications other than site visits- letters/ meeting notes/ notes of telephone calls** ☐
    (To document any agreements or significant discussions regarding trial administration, protocol violations, trial conduct, adverse event (AE) reporting)
20. **Source documents/ Signed, dated and completed case report forms (CRF)** ☐
    (To document the existence of the subject and substantiate integrity of trial data collected. To include original documents related to the trials, to medical treatment, and history of subject)
21. **Documentation of CRF corrections** ☐
    (To document all changes / additions or corrections made to CRF after initial data recorded)
22. **Interim or annual reports to IEC and authority(ies)** ☐
23. **Subject screening log** ☐
    (To document identification of subjects who entered pre-trial screening)
24. **Subject identification code list** ☐
    (To document that investigator / Institution keeps a confidential list of names of all subjects allocated to trial numbers on enrolling in the trial. Allows investigator/ Institution to reveal identity of any subject)

25. **Subject enrolment log** ☐

    (To document chronological enrolment of subjects by trial number)

26. **Investigational products accountability at the site** ☐

27. (To document that investigational product(s) have been used according to the protocol)

28. **Signature sheet** ☐

    (To document signatures and initials of all persons authorised to make entries and / or corrections on CRFs)

29. **Record of retained body fluids/ tissue samples (if any)** ☐

    To document location and identification of retained samples if assays need to be repeated

<u>After Completion or Termination of the Trial</u>

After completion or termination of the trial, all of the documents identified should be in the file together with the following

30. **Investigational product(s) accountability at site** ☐
    (To document that the investigational product(s) have been used according to the protocol. To documents the final accounting of investigational product(s) received at the site, dispensed to subjects, return by the subjects)
31. **Documentation of investigational product destruction** ☐
    (To document destruction of unused investigational products by sponsor or at site)
32. **Completed subject identification code list** ☐
    (To permit identification of all subjects enrolled in the trial in case follow-up is required. List should be kept in a confidential manner and for agreed upon time)
33. **Audit certificate (if available)** ☐
    (To document that audit was performed)
34. **Final trial close-out monitoring report** ☐
35. To document that all activities required for trial close-out are completed, and copies of essential documents are held in the appropriate files
36. **Treatment allocation and decoding documentation** ☐
37. (Returned to sponsor to document any decoding that may have occurred)
38. **Final report by investigator to IEC where required, and where applicable, to the regulatory authority(ies)** ☐
    To document completion of the trial