

The drug must not be used for clinical trials before it has passed inspection. Drug administration authorities may conduct random inspections on the investigational drug.

Article 37: Before conducting the clinical study, the applicant shall file with the SFDA information such as the clinical study protocol, name of the principal investigator of the leading institution, participating institutions and their investigators, approval letter from the ethics committee, and a sample of the Informed Consent Form, also providing a copy to the PDA where the institutions are located and the PDA where the application was filed.

Article 38: If an applicant discovers that an institution conducting a clinical study is in violation of relevant regulations, or is not following the clinical study protocol, the applicant shall try to correct the situation. For serious violations, the applicant may request to suspend or stop the clinical study and shall submit a written report to the SFDA and the relevant PDA(s).

Article 39: Upon completion of the clinical study, the applicant shall submit a clinical study summary report, statistical analysis report, and database to the SFDA.

Article 40: A clinical study shall start within 3 years of its approval. Otherwise the approval certificate shall automatically become null and void. A re-application must be submitted to resume the study.

Article 41: Should any serious adverse event occur during clinical trials, the institution should report to the PDA, SFDA, and the applicant within 24 hours of occurrence, and report to the Ethics Committee in a timely fashion.

Article 42: The SFDA may request the applicant to amend the clinical study protocol or to suspend or stop the clinical study in any of the following circumstances:

- 1) The Ethics Committee has failed to perform its duty
- 2) The safety of the subjects cannot be effectively ensured
- 3) A serious adverse event was not reported in a timely fashion
- 4) Evidence exists that the investigative drug is not effective
- 5) Quality problems exist in the drug used for clinical trials
- 6) Fraud is committed in the clinical study
- 7) Other circumstances violating *GCP*

Article 43: During the clinical study, in case a large-scale or unexpected adverse reaction or serious adverse event occurs, or if there is evidence to prove that the investigational drug has significant quality problems, the SFDA or PDA may adopt emergency mandatory administrative measures to suspend or stop the clinical study, and the applicant and institution must immediately stop the study.

Article 44: A foreign applicant who wants to conduct an international multi-center clinical study shall apply to the SFDA in accordance with the following provisions: