Annexure-7

REGULATORY GUIDANCE FOR CONDUCTING CLINICAL TRIALS IN INDIA

Currently clinical trials in India are regulated by Schedule Y of the Drug and Cosmetics Rules, 1945. During the amendment of Drugs and Cosmetics Rules, 2005, the Schedule Y was extensively revised to bring the Indian regulations on par with internationally accepted definitions and procedures. Schedule Y defines the requirements and guidelines for import and/or manufacture of new drugs for sale or for clinical trials. The Central Drugs Controls Standards Organization (CDSCO) office has issued guidance document on clinical trial inspection effective from 01 Nov 2011.

REGULATORY REQUIREMENTS FOR CLINICAL STUDY

1. If the sponsor is a foreign company, organization or person(s) – it shall appoint a local representative or Clinical Research Organization (CRO) to fulfill the appropriate local responsibilities as governed by the Indian regulations.
2. The Sponsor may transfer any or all of the Sponsor's study related duties and functions to a CRO but the ultimate responsibility for the quality and the integrity of the Study Data shall always reside with the Sponsor.
3. Any Study related duty, function or responsibility transferred to and assumed by a local representative or a CRO should be specified in writing. Any study related duties, functions or responsibilities not specifically transferred to and assumed by a CRO or a local representative shall be deemed to have been retained by the Sponsor.
4. The sponsor should utilize the services of qualified individuals e.g. bio-statisticians, clinical pharmacologists, and physicians, as appropriate, throughout all stages of the study process, from designing the protocol and CRFs and planning the analyses to analyzing and preparing interim and final clinical study reports.
5. For new drug substances discovered in India, clinical trials are required to be carried out in India right from Phase I and data should be submitted as per the requirement.
6. For new drug substances discovered in countries other than India, Phase I data will be required from the other country and should be submitted along with the application. After submission of Phase I data generated outside India to the Licensing Authority, permission may be granted to repeat Phase I trials and/or to conduct Phase II trials and subsequently Phase III trials concurrently with other global trials for that drug. Phase III trials are required to be conducted in India before permission to market the drug in India is granted.
7. Application (Form 44 and Appendix-01) for the purpose of conducting clinical trial in India requires submission of documents as per Schedule Y (Table-01)

Table-01: Checklist for Permission For Conducting Clinical Trial (Phase I, II, III) And Global Clinical Trial For Biological Application

Name of the Applicant
Drug
Dosage form, Composition and packing details
Form 44
TR Challan
Sponsor's name and Authorization letter
Chemical and Pharmaceutical/CMC information
Pre-clinical data
Animal Pharmacological data as per Appendix IV to Schedule Y
Animal Toxicological data as per Appendix III to Schedule Y
Study Protocol
Protocol Number
Phase of the study
Study Rationale
Undertaking by investigators as per Appendix VII to Schedule Y

Name and No. of Centres and Investigators
No. of patients to be enrolled
Globally
India
Name/Numbers of countries participating in study
Regulatory status/Approval from participating countries including Institutional review Board approvals
Investigator's Brochure
Case report Form
Informed Consent of subjects/volunteers as per appendix V to Schedule Y
Doc. As per CDSCO guidance doc.
Complete Phase I, II study report if Phase III permission is required
Phase I if Phase II permission is required
Suspected Unexpected Adverse Reactions (SUSARs)
Affidavit from the sponsor that the study has not been discontinued in any country

8. The clinical protocol must be reviewed and approved by an Institutional Ethics Committee of all participating sites. The anticipated timeline for the approval of conduct of the study is around 8-12 weeks if direct approval is granted. But if it is a new drug/First in human trials the applications are referred to the Investigational New Drugs committee which would take anywhere from 12 – 24 weeks to give their opinion. Based on this opinion the Drug Controller General of India (DCGI) office may approve (with or without some changes to the protocol) or seek clarifications or decline approval.
9. Import License/Test License in Form 11 is obtained from DCGI whenever, the clinical study drugs, biological samples, diagnostics kits are to be imported for the purpose of tests and analysis during the conduct of Clinical trials / Bioavailability/Bioequivalence (BA-BE) studies. The documents to be submitted for the Import License include
    - Application with Form 12
    - Purpose of import and detailed utilization indicating nature of tests and quantity required for each test.
    - Authorization letter from the sponsor for the Import License
    - Justification and Utilization break up

10. When biological samples (e.g. blood, serum, plasma, urine, etc) are required to be collected during the clinical trial and exported out of the country for analysis, a "No Objection Certificate" (NOC) has to be obtained from DCGI. The application is applied to the DCG(I) with the following information
    - type of sample
    - shipment details
    - address of the laboratory where analysis to be conducted
    - purpose of the export of biological sample

    The Export NOC could also be applied parallel with the clinical study approval.