GUIDANCE DOCUMENTS FOR REGULATORY SUBMISSIONS

In an effort to help stakeholders get over the regulatory complexities involved in their interactions with the Health Authorities, ministries or regulators, Indian Society for Clinical Research (ISCR) has attempted to provide a gist of the various process documents that are required for submission in the various categories of trials and what needs to be done / submitted, in a simple, easy to understand format.

DISCLAIMER

For document see below

The comments received from various firms and associations were examined and the following requirements were finalized for submission of applications for Global Clinical Trials. The applicants are advised to make applications as per the requirements adherent to the serial numbers given below.

As agreed earlier at the meeting at IDMA office on 17thOctober, 2006 in Mumbai, applications would be scrutinized as mentioned above from 1st December, 2006. The applications, if non-compliant with the requirements mentioned below, shall be rejected.

Requirements For Filing **Applications for** Global Clinical Trial
(for submission of data to countries other than India also)

1. Name of the Applicant
2. Authorization letter from the Sponsor
3. Name of the Drug
4. Regulatory status of the drug in other countries (Names of countries where the drug is approved along with international package insert or where IND application is filed)
5. Objective of the Study
6. Phase of Study
7. Names of theParticipating Countries /Investigator sites
8. Total no. of patients to be enrolled globally
9. No. of investigator sites to be enrolled in India
10. No. of patients to be included in India
11. Regulatory/ IRB approvals from participating countries
    (these approvals should be submitted along with their English translation and reason in case the company is submitting an expired IRB/ IEC approval)

12. Status of the study in other countries

    (this should include no. of patients enrolled, no. patients completed the study and no. of patients discontinued)

13. Suspected Unexpected Serious Adverse Reaction (SUSAR) from other participating countries if any reported

14. Affidavit from the sponsor that the study has not been discontinued in any country and in case of discontinuation the reasons for such a discontinuation and that the applicant would further communicate to DCG (I) about future discontinuation

15. Data Submitted

    a) Chemical and Pharmaceutical data

        i) Generic name and chemical name

        ii) Dosage form

        iii)Composition

    b) Animal Pharmacology Data

    c) Animal Toxicology data

    d) Clinical data

        i) Phase I

        ii) Phase II

        iii) Phase III

        iv) Phase IV

e) Rationale for selecting the proposed dose(s) and indication(s)

16. Documents Submitted

a) Form 44 and Treasury chalan

b) Form 12 and Treasury chalan

c) Details of Biological specimens to be exported

d) Protocol

e) Informed Consent Documents (ICD)

f) Case Report form

g) Investigator's Brochure duly supported by an affidavit that the summarized information submitted is based on facts

h) Undertakings by the Investigators

i) Ethics committee approvals (if already available)

PROTOCOL AMENDMENTS

a. Those amendments which do not require notification to or permission of the Licensing Authority

- **i) Administrative and Logistic changes**
- **ii) Minor protocol amendments and additional safety assessments in case the institutional ethics committee has already approved these changes**

b. Those amendments which require notification to the Licensing Authority but need not wait for permission

- **i) Additional Investigator sites**
- **ii) Change in investigator with the consent to withdraw from the earlier investigator**
- **iii) Amended Investigators Brochure, amended informed consent**

c. Those amendments which require prior permission of the Licensing Authority

- **i) Additional Patients to be recruited**
- **ii) Major changes in protocol with respect to study design, dose and treatment options**
- **iii) Any change in inclusion or exclusion criteria**

Note: All amendments must be approved by the concerned Institutional Ethics Committee before their implementation