Pharmaceutical Regulatory Affairs: Open Access

ISSN: 2167-7689

Ramu et al., Pharmaceut Reg Affairs 2015, 4:2
DOI: 10.4172/2167-7689.1000140

Review Article Open Access

Current Regulatory Scenario for Conducting Clinical Trials in India

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Introduction

India with well trained skilled professionals and vast Pharma companies offers unique opportunities for conducting clinical trials. Due to significant cost reduction and increased pace and productivity of all R&D phases has brought considerable growth and impact to the favorable regulatory climate for conducting the clinical trials in India. Various institutions playing a prominent role in guiding the clinical trial in India include DCGI (drugs controller general of India), DBT (department of biotechnology), ICMR (Indian council of medical research, CBN (central bureau of narcotics), RCGM (review committee on generic manipulation) GEAC (genetic engineering approval committee) [1,2].

Current Drug Regulatory Procedures

Currently the clinical trials are regulated by schedule Y of the drug & cosmetics rules, 1945.After the amendment of the D&C act in 2005, the schedule Y was extensively revised to bring the Indian regulations up to par with internationally accepted definitions and procedures. The changes which took place were

- Definitions for Phase I-IV trials, which eliminated the Phase lag.
- Clear responsibilities for investigators; and sponsors.
- Requirements for notifying changes in protocol.

The Central Drugs Standard Control Organization (CDSCO) under Ministry of Health and Family Welfare (MoH and FW) prescribes standards for ensuring safety, efficacy and quality of drugs, cosmetics, diagnostics and devices in India. Apart from these there are other Statutes and ministries that regulate the various aspects of drugs such as; the Poisons Act, 1919; the Pharmacy Act, 1948; the Drug and Magic Remedies (Objectionable Advertisement) Act, 1954;the Narcotic Drugs and Psychotropic Substances Act, 1985; the Insecticide Act, 1968; The Medicinal and Toilet preparation (Excise duties) Act, 1956 and The Drug (Price Control) Order, 1995 (under the essential commodities Act).Some more laws having a bearing on pharmaceutical manufacture, distribution and sale in India are The Industries (Development and Regulation) Act, 1951,The Trade and Merchandise Marks Act, 1958, The Indian Patent Act, 1970 and the Design Act, 2000 and the Factories Act, 1948 [3-7].

Clinical trials have been defined in Rule 122DAA of the Drugs & Cosmetics Act (D&C Act) in India as "Systemic study of new drugs in human subject(s) to generate data for discovery and/or verifying the clinical, pharmacological (including pharmacodynamics and pharmacokinetics) and/or adverse effects with the aim of determining safety and/or efficacy of the new drugs.

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. However for the 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 Page 3 of 5 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. Application for permission to start specific phase of clinical trial sponsor is required to submit application (Form 44) for the purpose of conducting clinical trial in India and submit documents as per Schedule Y of the Drugs and Cosmetics Act 1940 and Rules. A clinical trial application utilizes Form 44 [3] as given in table-01, accompanied by documents pertaining to chemical and pharmaceutical information, animal pharmacology, toxicology data and clinical pharmacology data. Other trial-related documents that must be submitted for approval include the Investigator's Brochure, trial protocol, case report form, informed consent form, investigator's undertaking. In addition, the trial's regulatory status of the trial in other countries must be reported. The clinical protocol must be reviewed and approved by an IEC of all participating sites. The requirements in respect of Chemistry and Pharmaceutical information has been elaborated separately for Biologicals while other requirement for conduction of Clinical trial and other requirements remains the same as per Schedule Y of Drugs and Cosmetic Rules 1945 (Table 1).

The checklist has been published by the CDSCO office for the conduct of phase I/II/II clinical trial as given in table-02 [5,6]. 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 IND committee which would take anywhere from 12-24 weeks to give their opinion. Based on this opinion the DCGI office may approve (with or without some changes to the protocol) or seek clarifications or decline approval 3 (Table 2).

Conclusion

Clinical trials are the key tools in new drug evaluation. India has signed the trade related intellectual property rights (TRIPS) agreement as a part of the WTO regulations to gearing up to attract more and more researchers from around the world to conduct clinical trails in India. Recent amendments in the regulatory requirements have shifted the thrust from just safeguarding the subjects to providing them for access for biomedical innovation. India is poised to offer the global pharmaceutical industry high quality & cost effective contract services to support drug discovery.

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Received April 25, 2015; **Accepted** May 19, 2015; **Published** May 26, 2015

Citation: Ramu B, Sathish Kumar M, Ramakrishna M (2015) Current Regulatory Scenario for Conducting Clinical Trials in India 4: 137. doi: 10.4172/2167-7689.1000140

Table 1 Form 44
Application for grant of permission to import or manufacture a New Drug or to undertake clinical trial.
I/We*…… (Name of the Authorised Person) of M/s.....…….. (Full address, Telephone no, Fax No and e-mail) hereby apply for grant of permission for import of and/or clinical trial or for approval to manufacture a new drug or fixed dose combination or subsequent permission for already approved new drug. The necessary information / data is given below :
I. Particulars of Subject device
I. Generic name
ii.Brand name
iii.Composition of device
iv. Specifications/standards of device
v. Qualitative and quantitative particulars of the constituents
vi. Information on sterility and stability of the product
vii. Labeling details
viii. Variations in shape, style or size of the device, if applicable
ix. Physician manual and promotional literature (Literature insert) in English. (If any)
x. Packaging description including pack sizes
xi. Risk classification (in country of origin as well as in 5 GHTF countries i.e. EU, USA, Japan, Canada, Australia)
xii. List of accessories or device to be used in conjunction with subject medical device
xiii. Indication w.r.t. Which clinical study is to be carried out
xiv. Name and address of the manufacturer/contract manufacturer(s)
xv. Regulatory status of the subject device (particularly in 5 GHTF countries i.e. EU, USA, Japan, Canada, Australia)
II.Technical data submitted along with the application as per Annex II. All the information provided with the application should be indexed properly with page no's.

Table 1: Form 44

Table 2 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 Centre's and Investigator's
No. of patient to be enrolled Globally
India
Name/Numbers of countries participating in study
Regulatory status/Approval from participating countries (mention date in case of US IND) including IRB 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
Complete Phase I, II study report if Phase III permission is required
Phase I if Phase II permission is required
SUSAR's Affidavit from the sponsor that the study has not been discontinued in any country

Table 2: Checklist for Permission For Conducting Clinical Trial (Phase I, II, III) And Global Clinical Trial For Biological Application.

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4. CDSCO. Application for grant of permission to import or manufacture a New Drug or to undertake clinical trial.

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6. CDSCO (1940) Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy Guidance for Industry.

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