

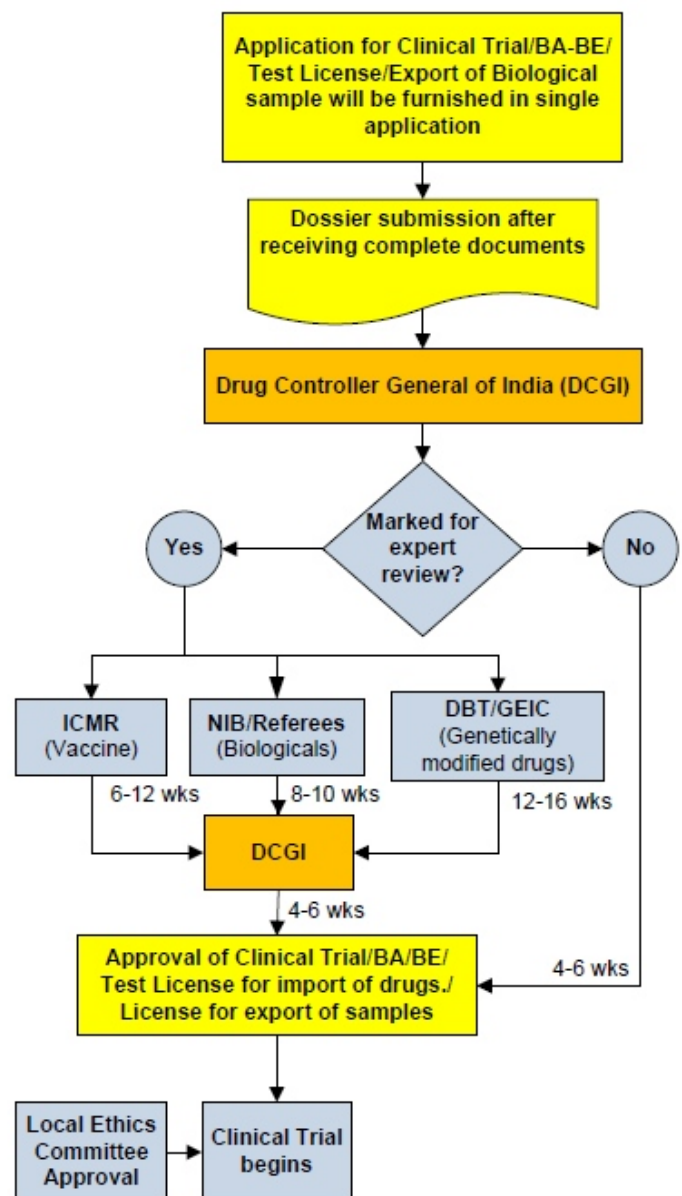


Regulatory in India

CDSCO - The Central Drugs Standard Control Organization (CDSCO) is the regulatory agency for drug development in India. CDSCO is central authority functioning under Directorate General of Health Services. At present the Drugs and Cosmetics Act, 1945 governs the conduct of Bioequivalence and Phase-I to Phase-IV studies in India. This act regulates the import, export, manufacture, distribution, sale and clinical research of drugs and cosmetics in India. Schedule Y of India's Drugs and Cosmetics Act which are equivalent to the Code of Federal Regulations in the United States, harmonizes with the International Conference on Harmonization standards in areas such as documentation, patient safety, reports of patient safety, reports of adverse events, constitution of ethics committees, standard operating procedures and provision for the government to monitor clinical trials in India.

Under the Drug and Cosmetics Act, the senior most officer, (Drugs Controller General of India, DCGI) of Central Drugs Standard Control Organization (CDSCO), is responsible for approval of New Drugs and Clinical Trials to be conducted in India.

REGULATORY PROCESS FLOW



REGULATORY APPROVAL TIMELINES

Regulatory Body	Approval	Time
Drugs Controller General of India(DCGI)	Regulatory approval for study conduct in India	Category A- 4- 8 weeks Category B- 8 - 12 weeks
Local Ethics Committees	Ethics committee approval by the various study sites	4 - 12 weeks (in parallel)
Drugs Controller General of India(DCGI)	Test License to import trial supplies	2 weeks (along with CT-NOC)
Total (FPFV)	N.A.	12 weeks
Directorate General of Foreign Trade (DGFT / DCGI)	Permission to export blood samples outside India	Additional 2-4 weeks
Genetic Engineering Approval Committee (GEAC)	Approvals for studies using r-DNA products	Additional 12 to 14 weeks

Data for Application Clinical Trials / Import / Manufacture of New Drugs for Marketing

- Introduction
- Chemical and Pharmaceutical Information
- Animal Pharmacology
- Animal Toxicology
- Human/Clinical Pharmacology (Phase I)
- Therapeutic Exploratory Trials (Phase II)
- Therapeutic Confirmatory Trials (Phase III)
- Special Studies
- Regulatory Status in Other Countries
- Prescribing Information
- Samples and Testing Protocols

Information required for Global Clinical Trial Application

1. Name of the applicant
2. Authorization letter from the sponsor
3. Name of the study drug
4. Regulatory status of the drug in other countries
 - Names of countries where the drug is approved
 - Approvals should be submitted with English translation
 - International package insert
 - name of countries where IND application is filed
5. Objective of the study
6. Phase of study
7. Names of the participating countries & 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. IRB approvals from participating countries:
 - Approvals should be submitted with English translation
12. Status of the study in other countries:
 - Number of patients
 - Enrolled
 - Completed in the study
 - Discontinued
13. SUSAR from other participating countries, if any reported
14. Affidavit from the sponsor that the study has not been discontinued in any country
15. Inv. Brochure duly supported by an affidavit that the summarized information submitted is based on facts

Clinical Documents and Forms

- Protocol
- Informed Consent Documents (ICD)
- Case Report form
- Investigator's Brochure
- Form 44 and Treasury challan*
- Form 12 and Treasury challan*
- Details of Biological specimens to be exported
- Undertakings by the Investigators
- CV of the investigators
- Ethics committee approvals (if already available)

For new drug discovered in other countries Phase I trials are not usually allowed to be initiated in India. However, such trials may be permitted even in the absence of Phase I data from other countries if the drug is of special relevance to the health problem of India.

SAE/ SADR/ PSUR Timelines for reporting SAE/SADR

Report all unexpected SAE/SADR to the Sponsor in 24 hrs
Report all SAE/SADR to EC within 7 working days
Report all SAE/SADR to DCGI within 14 calendar days

PSUR (Periodic Safety Update Reports): To be submitted for all new drugs

PSUR shall be submitted every 6 months for the 1st 2 years after approval
For subsequent 2 years- PSUR need to be submitted annually

* - Payment Receipt

For additional inquiries or questions, please contact:

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