Clinical Trial Regulations in India

Schedule Y

Guidance for import and/or manufacture of new drug for clinical trials or marketing in India

Module 5 Topic 3_5

Schedule Y

- Schedule Y is a guidelines for import and/or manufacture of new drug for clinical trials or marketing in India
- Objective:
  - To frame guidelines for conduct of clinical research control and regulation for new drugs
- Authorities:
  - Central Drugs Standard Control Organization (CDSCO) and Drug Testing Advisory Board (DTAB)

Schedule Y

Sub-sections of schedule Y for import and/or manufacture of new drug for clinical trials or marketing in India

- 122-A: Application for permission to import new drug
- 122-B: Application for approval to manufacture new drug
- 122-D: Permission to import or manufacture fixed dose combination
  - 122-DAA: Application for permission to conduct clinical trials for New Drug/Investigational New Drug
    - 122-DAB: Compensation in case of injury or death during clinical trial
    - 122-DAC: Permission to conduct clinical trial

Schedule Y

- 122-D: Permission to import or manufacture fixed dose combination (contd)
  - 122-DB: Suspension or cancellation of Permission/Approval
  - 122-DC: Appeal
  - 122-DD: Registration of Ethics Committee
  - 122-E: Definition of new drug

Schedule Y

Application for permission to import or manufacture new drug (122-A & B)

- Chemical and pharmaceutical information
- Human / Clinical Animal Pharmacology
- Animal toxicology
- Pharmacology (Phase I)
- Therapeutic exploratory trials (Phase II)
- Therapeutic confirmatory trials (Phase III)
- Special studies
- Regulatory status in other countries
- Prescribing information

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Application for permission to import or manufacture new drug (122-A & B)

- Chemical and Pharmaceutical Information
  - Information on active ingredients
  - Drug information (Generic Name, Chemical Name)
  - Physical and chemical properties of drug
  - Analytical Data
  - Complete monograph specification including Validations & Stability Studies
  - Data on Formulation, Dosage form, Composition, Excipient compatibility study

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Application for permission to import or manufacture new drug (122-A & B)

- Animal Pharmacology
  - Specific pharmacological actions
  - General pharmacological actions
  - Follow-up and Supplemental Safety Pharmacology Studies
  - Pharmacokinetics: absorption; distribution; metabolism; excretion

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Application for permission to import or manufacture new drug (122-A & B)

- Animal Toxicology
  - Systemic Toxicity studies
  - Single dose toxicity studies
  - Repeated dose toxicity studies
  - Male fertility studies
  - Female Reproduction and Developmental Toxicity Studies
  - Local toxicity, Allergy/Hypersensitivity
  - Genotoxicity & Carcinogenicity

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122-DAA: Application for permission to conduct clinical trials for New Drug/Investigational New Drug

"Clinical trial" means a systematic study of new drug(s) in human subject(s) to generate data for discovering and/or verifying the clinical, pharmacological (including pharmacodynamic and pharmacokinetic) and/or adverse effects with the objective of determining safety and/or efficacy of the new drug."

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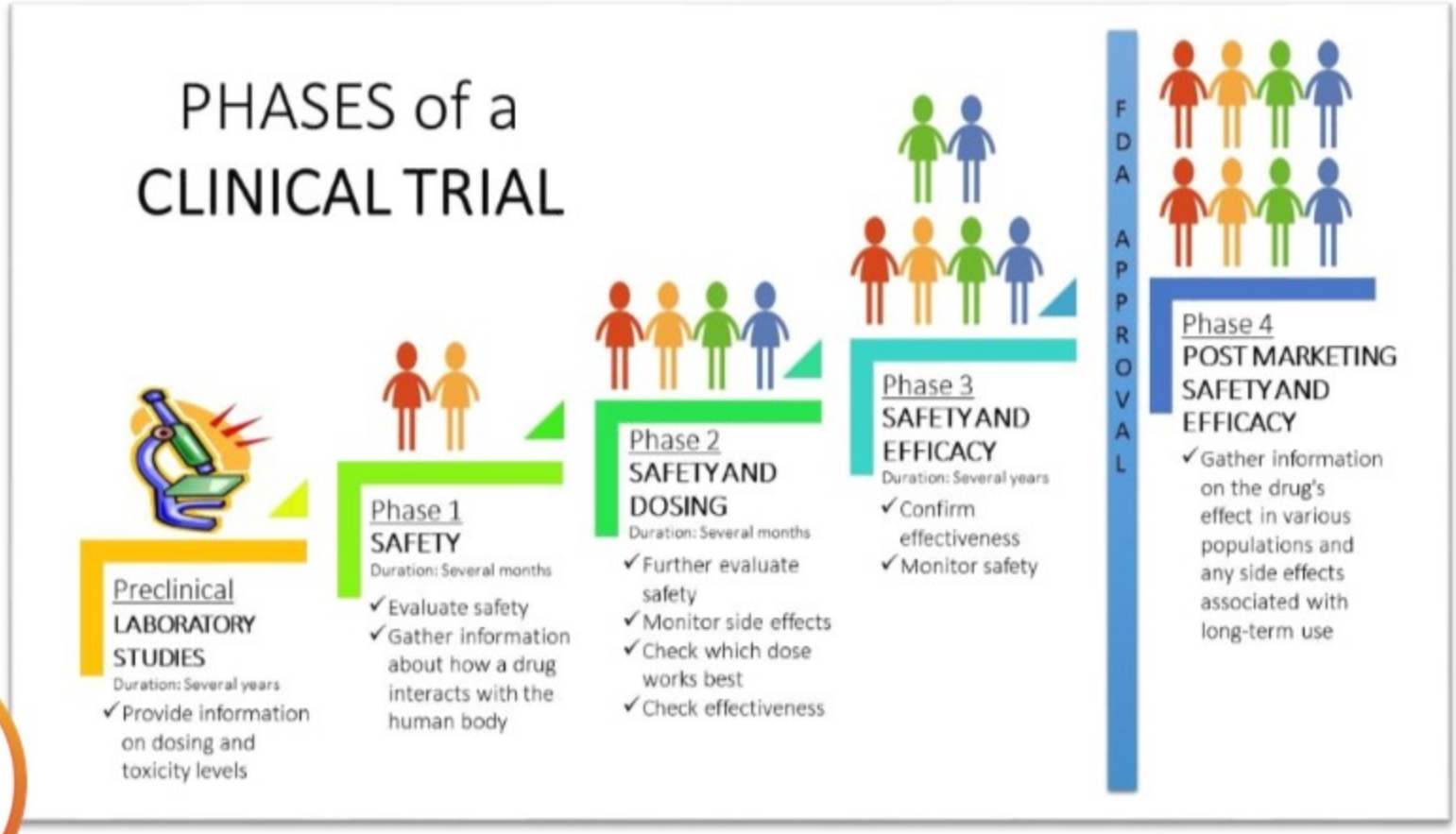
122-E: Definition of new drug

New Drug A new substance of chemical, biological or biotechnological origin, in bulk or prepared dosage form; used for prevention, diagnosis, or treatment of disease in man or animal; which except during local clinical, trials, has not been used in the country to any significant extent and which except during local clinical trials, has not been recognised in the country as effective and safe for the proposed claims.

Schedule Y


PHASES of a
CLINICAL TRIAL
Preclinical
LABORATORY STUDIES
Duration: Several years
✓Provide information on dosing and toxicity levels
Phase 1
SAFETY
Duration: Several months
✓Evaluate safety
✓Gather information about how a drug interacts with the human body
Phase 2
SAFETY AND DOSING
Duration: Several months
✓Further evaluate safety
✓Monitor side effects
✓Check which dose works best
✓Check effectiveness
Phase 3
SAFETY AND EFFICACY
Duration: Several years
✓Confirm effectiveness
✓Monitor safety
FDA APPROVAL
Phase 4
POST MARKETING SAFETY AND EFFICACY
✓Gather information on the drug's effect in various populations and any side effects associated with long-term use

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- Approval
  - The ethics committee
  - Licensing Authority
- Sponsor
  - Quality assurance
  - Submission of status report
  - Reporting of any serious adverse effect
  - To ensure that laboratories used for generating data for clinical trials should be compliant with Good Laboratory Practices

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- Investigator
  - Conduct of the trial according to the protocol and the GCP Guidelines
  - Follow the SOP's
  - Ensure that adequate medical care is provided to the participant for any adverse events

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122-DAB: Serious Adverse Events

- Any undesirable experience associated with the use of a medical product in a patient
- It should be reported within 14 days by the Sponsor to the Licensing Authority and to the other Investigator(s) participating in the study

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122-DD Registration of Ethics Committee (EC)

- It is the responsibility of the ethics committees that reviews and accords its approval to a trial protocol to safeguard the rights, safety and well being of all trial subjects.

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122-DD Registration of Ethics Committee (EC) (contd)

- The number of persons in an Ethics Committee should have at least seven member
  1. Chairperson outside the institution
  2. Member Secretary
  3. Basic medical scientists (preferably one pharmacologist)
  4. Clinicians
  5. Legal expert
  6. Social scientist/ representation of nongovernmental voluntary agency / philosopher / ethicist / theologian or similar person
  7. Lay person from the community

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Informed Consent Form

- In all clinical trials freely given, informed written consent is required to be obtained from each study subject
- Verbal information of the study using a patient information sheet
- Language that is nontechnical and understandable by the study subject
- Where a subject is not able to give informed consent, the same may be obtained from a legally acceptable representative

Schedule Y

Studies In Special Population

- Geriatrics
- Pregnant or nursing women
- Paediatrics
- Patients with kidney and Liver impairment, COPD/asthma, diabetes, cardiac disorders etc.

References

- The Drugs And Cosmetics Act, 1940) (23 OF 1940) (As amended up to the 31st December, 2016)
- The Drugs And Cosmetics Rules, 1945 (As amended up to the 31st December, 2016)