IND Enabling Studies (IND Studies)

Definition of IND

Full Form

- IND stands for Investigational New Drug.

Definition

- An Investigational New Drug (IND) application is a regulatory submission made to health authorities to obtain permission for testing a new drug in humans through clinical trials.
- **IND contains complete information about:**
  - Drug composition
  - Pharmacological studies
  - Toxicological studies
  - Manufacturing information
  - Clinical trial protocols
- IND is submitted before starting human clinical trials.

Types of IND



A. Commercial IND

- Commercial IND is submitted by pharmaceutical companies for drug development and marketing purposes.

B. Research IND

- Research IND is submitted by investigators or research institutions for scientific studies.

C. Emergency Use IND

- Emergency IND allows the use of an investigational drug in emergency situations when no approved treatment is available.

Regulatory Authorities

A. United States

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- IND application is submitted to the US FDA (Food and Drug Administration).

B. India

- IND-related clinical trial applications are submitted to CDSCO.

Purpose of IND

- The main purpose of IND is to ensure that the investigational drug is reasonably safe for administration to humans.

Importance of IND

A. Ensures Human Safety

- IND studies help identify possible toxic effects before administration to humans.
- These studies reduce the risk of severe adverse reactions during clinical trials.

B. Regulatory Permission for Clinical Trials

- Human clinical trials cannot begin without IND approval from regulatory authorities.

C. Evaluation of Drug Safety

- **IND submission provides detailed information about:**
  - Acute toxicity
  - Chronic toxicity
  - Genotoxicity
  - Reproductive toxicity
  - Safety pharmacology

D. Helps in Dose Selection

- Preclinical toxicity data help determine safe starting doses for human studies.

E. Assessment of Risk-Benefit Ratio

- Regulatory agencies evaluate whether the expected benefits justify the potential risks.

F. Ensures Scientific Quality

- IND studies follow standardized protocols and GLP guidelines.
- This improves reliability and reproducibility of data.

G. Supports Ethical Clinical Research

- Proper preclinical testing protects clinical trial participants.

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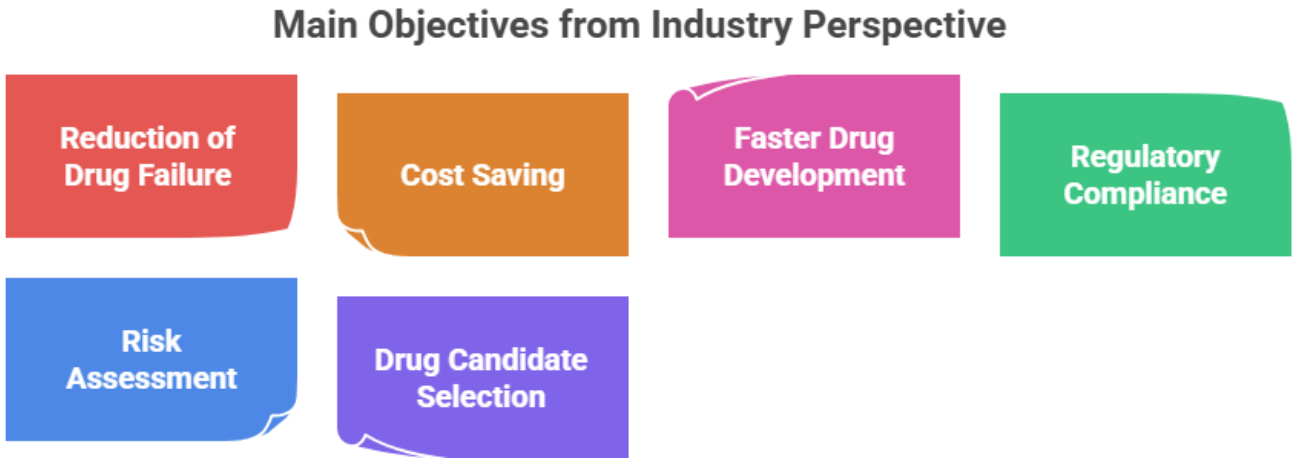
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Industry Perspective of IND Studies

Drug Development Process

- Pharmaceutical industries perform IND-enabling studies before starting clinical trials.
- IND studies are an important part of preclinical drug development.

Main Objectives from Industry Perspective



A. Reduction of Drug Failure

- Early toxicity testing helps industries identify unsafe compounds before expensive clinical trials.

B. Cost Saving

- Detecting toxicity during preclinical studies reduces financial loss caused by failure during human trials.

C. Faster Drug Development

- Properly planned IND studies help accelerate regulatory approval and clinical development.

D. Regulatory Compliance

- **Pharmaceutical companies must follow:**
  - OECD guidelines.
  - ICH guidelines.
  - GLP principles.
  - FDA requirements.

E. Risk Assessment

- **IND studies help companies evaluate:**
  - Risk-benefit ratio.
  - Safety margin.

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- Therapeutic index.

F. Selection of Drug Candidate

- Multiple compounds may be screened during early development.
- IND studies help select the safest and most effective candidate for clinical trials.

Importance of GLP in Industry

- Industries conduct IND studies under Good Laboratory Practice (GLP) conditions.
- **GLP ensures:**
  - Reliable data.
  - Proper documentation.
  - Regulatory acceptance.

Role in Regulatory Submission

- **Successful IND studies provide scientific evidence required for:**
  - IND application.
  - Clinical trial authorization.
  - Further drug development.

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IND Enabling Studies

Definition

- IND enabling studies are preclinical studies conducted to generate safety and efficacy data required for IND submission.
- These studies evaluate whether a drug candidate is safe enough for human testing.

Objectives

A. To Evaluate Drug Safety

- Toxic effects of the investigational drug are identified.

B. To Study Pharmacological Activity

- Desired therapeutic effects are evaluated.

C. To Determine Safe Starting Dose

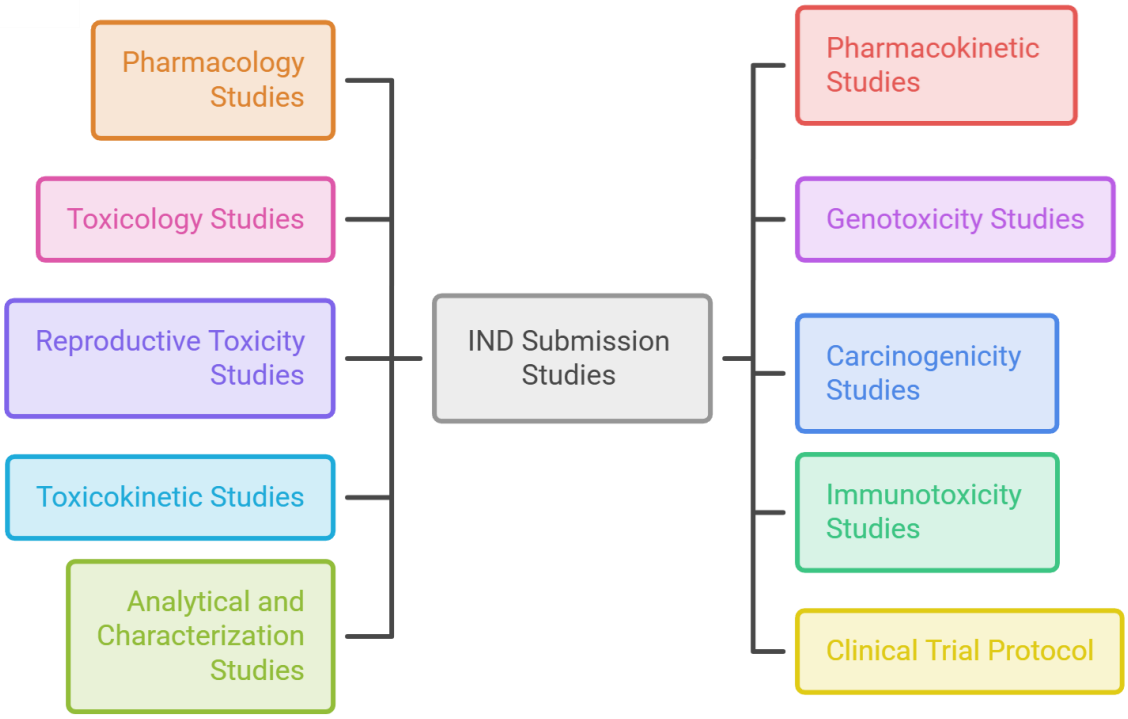
- Animal toxicity studies help estimate initial human dose.

D. To Support Regulatory Submission

- Data generated are submitted to regulatory authorities for approval.

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List of Studies Needed for IND Submission



A. Pharmacology Studies

1. Primary Pharmacodynamic Studies

- These studies evaluate desired therapeutic effects of the drug.

2. Secondary Pharmacodynamic Studies

- These studies identify additional pharmacological effects.

3. Safety Pharmacology Studies

- Effects on vital organ systems are evaluated.
- **Systems Commonly Studied**
  - Cardiovascular system
  - Respiratory system
  - Central nervous system

B. Pharmacokinetic Studies (ADME Studies)

Definition

- These studies evaluate movement of drugs inside the body.

Components

a) Absorption

- Study of drug entry into the body.

b) Distribution

- Study of drug distribution to tissues and organs.

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