Non-Clinical Drug Development

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Definition

- Non-clinical drug development refers to the stage of drug development in which laboratory and animal studies are conducted to evaluate the safety, pharmacological activity, and toxicity of a drug before it is tested in humans.



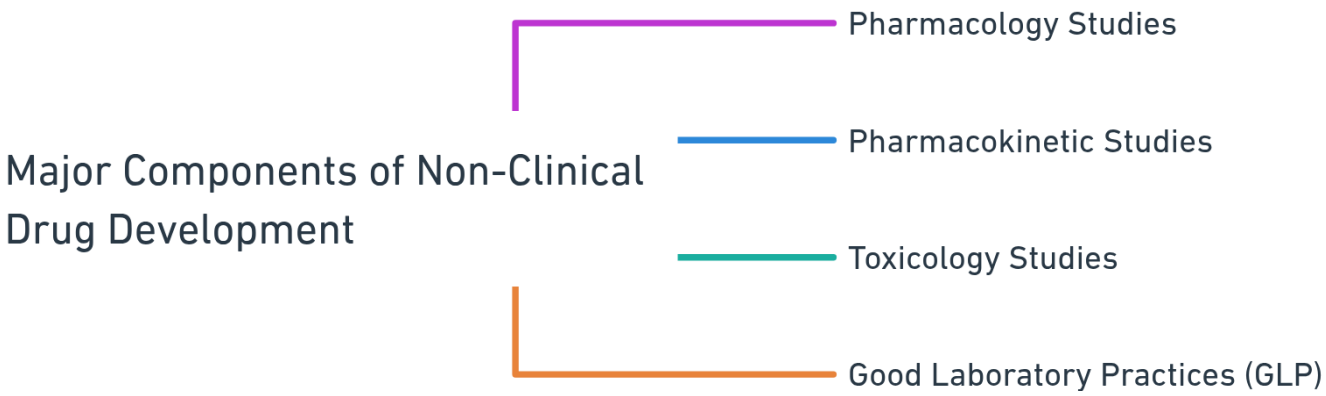
- These studies are performed before clinical trials and provide the scientific data required to obtain regulatory permission to start human studies.

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Purpose of Non-Clinical Drug Development

- To evaluate whether the drug candidate is safe enough to be tested in humans.
- To understand the mechanism of action and pharmacological effects of the drug.
- To determine the toxic effects and safe dosage range.
- To provide data required for submission of Investigational New Drug (IND) application.

Major Components of Non-Clinical Drug Development



1. **Pharmacology Studies**
   - These studies evaluate the biological activity of the drug.
   - Types of pharmacology include:

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A. **Primary pharmacology**
   - Determines the intended therapeutic effect of the drug.
   - **Example:**
     - Testing an antihypertensive drug to observe reduction in blood pressure.

B. **Secondary pharmacology**
   - Evaluates other effects of the drug unrelated to the primary therapeutic action.

C. **Safety pharmacology**
   - Evaluates potential effects on vital systems such as:
     - Cardiovascular system
     - Respiratory system
     - Central nervous system

2. Pharmacokinetic Studies

- These studies determine how the drug behaves inside the body.
- **Pharmacokinetic studies include:**

A. **Absorption**
   - How the drug enters the bloodstream.

B. **Distribution**
   - How the drug spreads through body tissues.

C. **Metabolism**
   - How the drug is chemically modified in the body.

D. **Excretion**
   - How the drug is eliminated from the body.

3. Toxicology Studies

- Toxicology studies evaluate potential harmful effects of the drug.
- **Important toxicology tests include:**

A. **Acute toxicity studies**
   - Evaluate harmful effects after a single dose.

B. **Sub-acute toxicity studies**
   - Evaluate toxicity after repeated doses for a short duration.

C. **Chronic toxicity studies**

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- Evaluate long-term toxicity after prolonged drug exposure.

D. Carcinogenicity studies

- Evaluate the potential of the drug to cause cancer.

E. Mutagenicity studies

- Determine whether the drug causes genetic mutations.

F. Reproductive toxicity studies

- Evaluate effects on fertility, pregnancy, and fetal development.

4. Good Laboratory Practices (GLP)

- Non-clinical studies must follow Good Laboratory Practices to ensure reliability and quality of data.
- **GLP ensures:**
  - Proper laboratory procedures
  - Accurate documentation
  - Quality control of experiments
  - Traceability of data

Importance of Non-Clinical Drug Development

- Ensures drug safety before human exposure.
- Provides scientific evidence for regulatory submissions.
- Helps determine safe dose ranges for clinical trials.

Global Submission of Investigational New Drug (IND)

Definition of IND

- IND stands for Investigational New Drug application.
- It is submitted to regulatory authorities to obtain permission to start clinical trials in humans.

Purpose of IND

- To demonstrate that the drug is reasonably safe for human testing.
- To provide regulators with information about drug composition, manufacturing, and preclinical studies.

Types of IND Applications

1. Commercial IND

- Submitted by pharmaceutical companies planning to develop and market a drug.

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2. Investigator IND

- Submitted by individual researchers or physicians conducting clinical research.

3. Emergency IND

- Used when a patient requires immediate treatment with an investigational drug.

Contents of IND Application

The IND application typically contains three major sections.

1. Animal Pharmacology and Toxicology Data

- **Includes results from:**
  - Pharmacology studies
  - Toxicology studies
  - Safety pharmacology studies
- These data help regulators evaluate safety of the drug before human trials.

2. Manufacturing Information

- **Includes:**
  - Composition of the drug
  - Manufacturing process
  - Quality control tests
  - Stability data
- This information ensures that the drug is consistently manufactured and safe for clinical trials.

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3. Clinical Protocols and Investigator Information

- **Includes**:
  - Clinical trial design
  - Objectives of the study
  - Inclusion and exclusion criteria for patients
  - Investigator qualifications

Global IND Submissions

- Different countries require similar documentation but follow different regulatory procedures.
- **Examples:**
  - USFDA – IND submission required before clinical trials
  - European Union – Clinical Trial Application (CTA) required
  - Japan – Clinical trial notification submitted to PMDA

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Global Submission of New Drug Application (NDA)

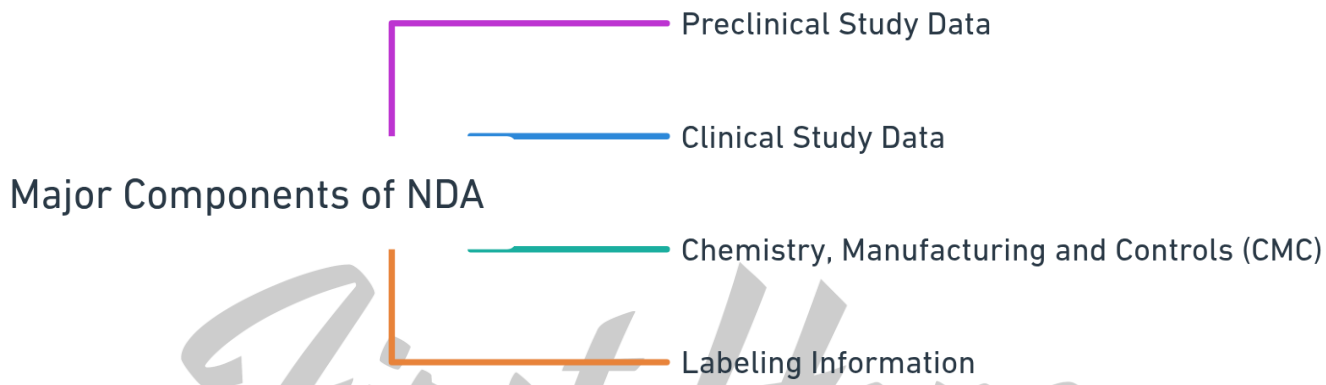
Definition of NDA

- NDA stands for New Drug Application.
- It is submitted to regulatory authorities to obtain approval for marketing a new pharmaceutical product.

Purpose of NDA

- To demonstrate that the drug is safe and effective for its intended use.
- To provide complete information about clinical studies, manufacturing, and labeling.

Major Components of NDA



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1. Preclinical Study Data

- **Includes results from:**
  - Pharmacology studies
  - Toxicology studies
  - Animal safety studies

2. Clinical Study Data

- **Includes results from clinical trials:**
  - Phase I – safety and dosage
  - Phase II – efficacy and side effects
  - Phase III – confirmation of effectiveness

3. Chemistry, Manufacturing and Controls (CMC)

- **Includes:**
  - Drug formulation details
  - Manufacturing processes
  - Quality control procedures
  - Stability studies

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