

Regulatory Approval Process

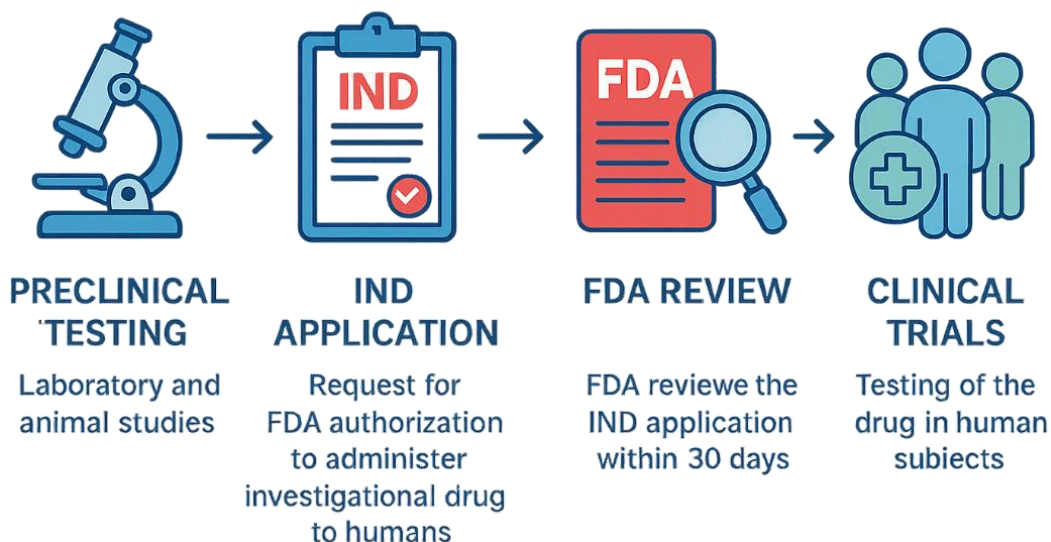
Investigational New Drug (IND) – Approval Process and Timelines

What is an IND?

- An Investigational New Drug (IND) application is a formal request submitted to the U.S. Food and Drug Administration (FDA) to obtain authorization to begin clinical trials in humans for a new drug that is not yet approved for marketing.
 - The IND ensures the investigational drug is safe for human administration before clinical testing.
 - No human testing can legally begin in the U.S. until the IND becomes effective.

INVESTIGATIONAL NEW DRUG (IND)

Approval process and timelines



Step-by-Step IND Approval Process

1. Preclinical (Animal) Studies

- Conducted in labs and animals to evaluate:
 - Pharmacology
 - Toxicology (safety profile)

2. Compilation of IND Application

- The IND submission includes:
 - **Animal Pharmacology & Toxicology Data:** Biological activity and safety in animals.
 - **Chemistry, Manufacturing, and Controls (CMC):** Manufacturing process and drug quality.

- **Clinical Protocols & Investigator Information:** Details of proposed Phase I trials, investigator qualifications, and site data.
- **Previous Human Experience:** If available, any earlier data on human use.

3. Submission of IND

- Submitted electronically or in paper form.
- **U.S. authority:** FDA
- **Other countries:** Respective regulatory agencies (e.g., EMA in Europe, CDSCO in India)

4. FDA (or Other Authority) Review

- IND is assigned a reference number.
- The FDA reviews the application within 30 calendar days.
- Review criteria:
 - Safety of human subjects
 - Adequacy of protocols
 - Manufacturing quality

5. Outcome

- If **no clinical hold** is issued within 30 days, the sponsor may initiate the clinical trial.
- If deficiencies exist, FDA may issue a clinical hold (partial or complete) and request changes or more information.

6. IND Amendments & Reporting

- **Protocol Amendments:** Required for trial or investigator changes.
- **Safety Reporting:** Prompt notification of serious adverse events (SAEs) or new animal data.
- **Annual Reports:** Yearly updates on study progress and findings.

Timelines

Stage	Approximate Timeline
Preclinical Studies	1–3 years
Pre-IND Meeting (optional)	~60 days to schedule and conduct
IND Submission	Based on sponsor's readiness
FDA Review of IND	30 calendar days
Institutional Review Board (IRB) Review	2–6 weeks
Clinical Trial Initiation	After 30 days + IRB approval

Reasons for FDA Clinical Hold

- Inadequate animal study data
- Unsafe or flawed clinical trial design
- Poorly defined protocols
- Unqualified investigators
- Manufacturing or quality control issues

Post-Submission Responsibilities

- Once IND is active and trials begin, the sponsor must:
 - Submit protocol amendments for any trial modifications.
 - Report adverse events, especially serious or life-threatening ones within 7–15 days.
 - Submit annual reports summarizing trial progress and safety.

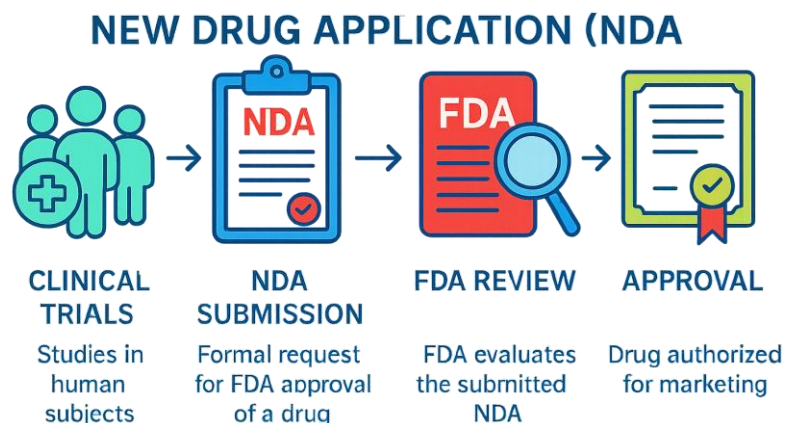
Types of IND Applications

1. **Commercial IND:** For companies seeking marketing approval.
2. **Research (Investigator) IND:** Filed by academic or clinical investigators.
3. **Emergency IND:** For unapproved drug use in urgent, life-threatening cases.
4. **Treatment IND:** For promising drugs in serious conditions before final approval.

New Drug Application (NDA)

Definition

- A New Drug Application (NDA) is a formal proposal submitted to the U.S. Food and Drug Administration (FDA) to request approval to market a new pharmaceutical product in the United States.
- The goal of an NDA is to demonstrate that the drug is:
 - Safe for use under prescribed conditions
 - Effective for its intended use
 - Manufactured with high quality standards





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