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Process of Drug Development

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Aim of new drug discovery process

- Developed chemically efficacious and safer drug
- Economically viable
- Discover entirely new class of drug
- Explore the mechanism

The Drug Development Process

- Each country has a drug regulatory body which governs the approval process
- India- CDSCO (central drugs standards and control organization)
- US- FDA (food and drug administration)
- UK- MHRA (medical and healthcare products regulatory agency)
- European Union- EMEA (European medicines agency)
- Drug must be proved to be **safe and effective**

Regulatory Agency

- Overlooks before and during various phases of product development and its marketing.
- The drug is tested:

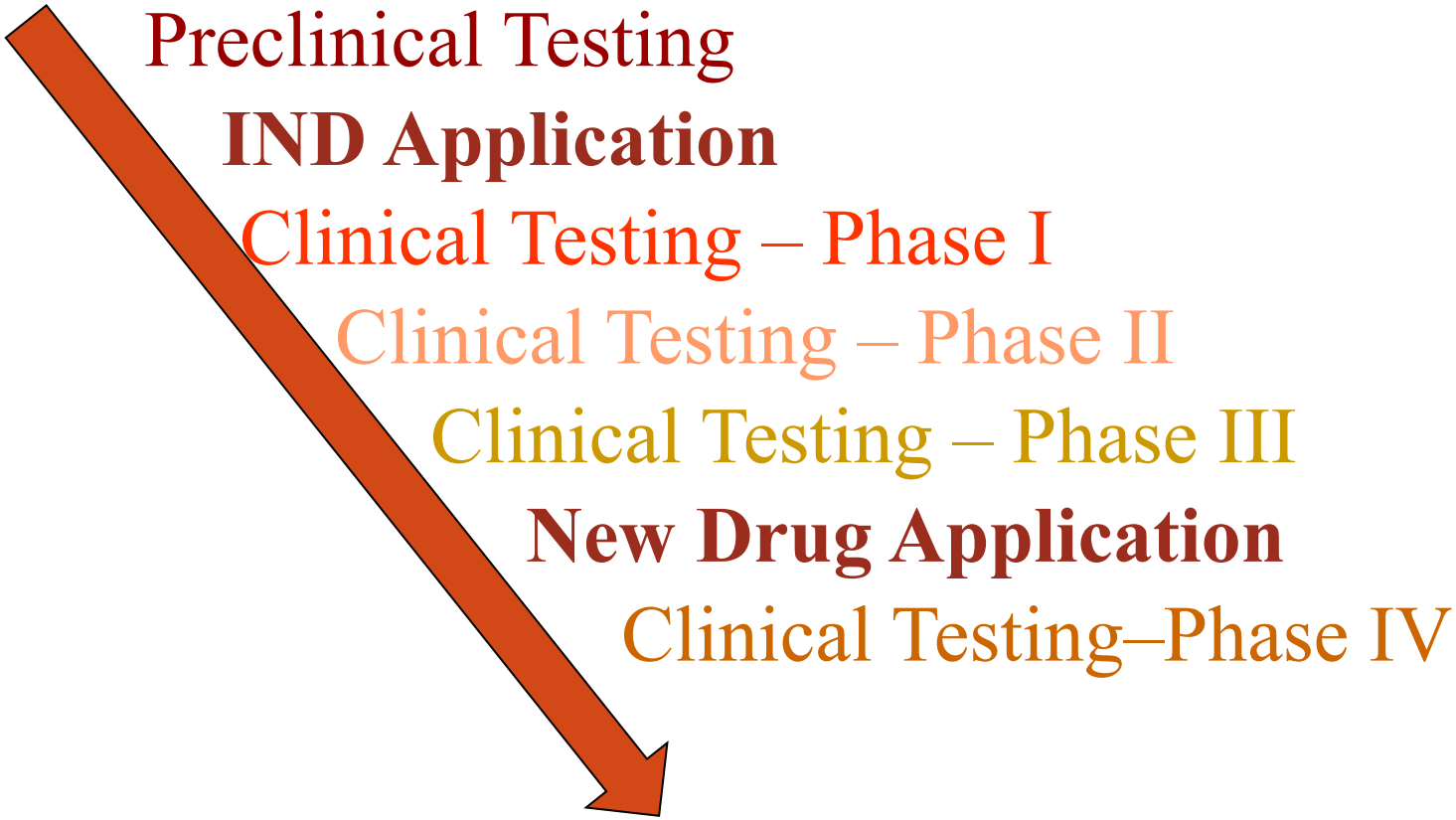
- **<u>Pre-clinical testing (laboratory and animals)</u>**
  - Pharmacology and toxicology

- **<u>Clinical testing (clinical trials in humans)</u>**
  - dose regime, safety and efficacy

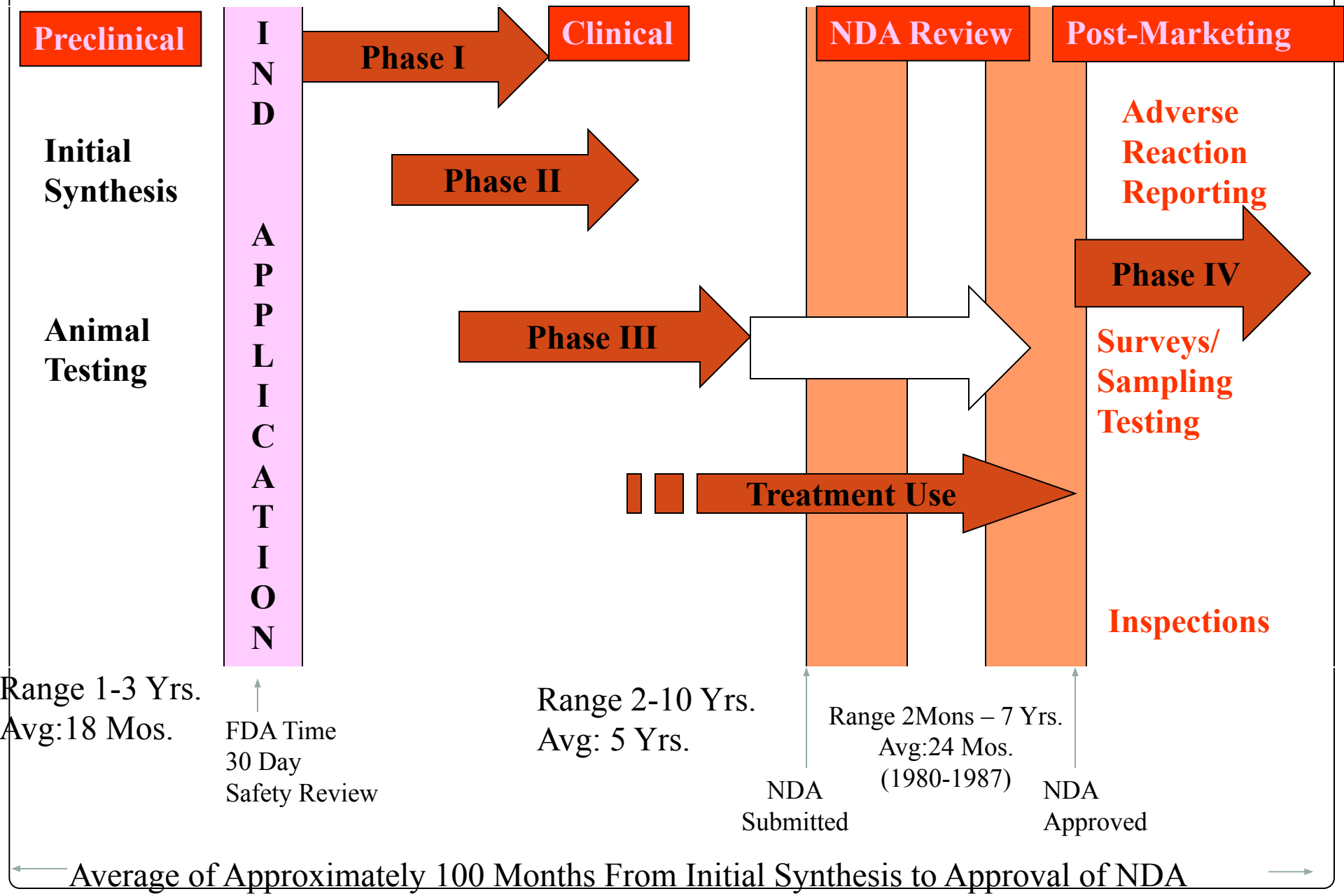
A High-Risk Undertaking

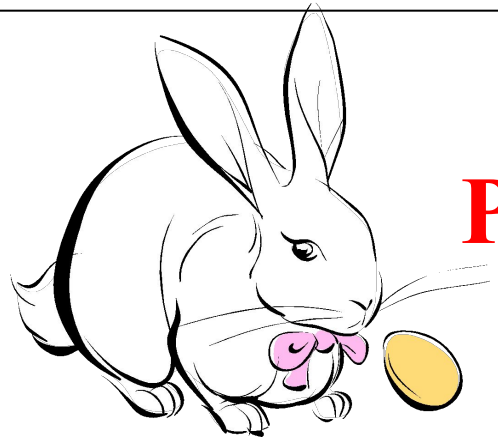
- **Time** 8-12 years from discovery to market.
- **Cost** average of $500-600 million.
- **Success** 1 in 4000 compounds synthesized or 1 in 5 tested in humans reaches the market.
- **Return** 1 in 3 drugs reaching the market recaptures development costs.

Major Stages of Drug Development



Drug Development Process





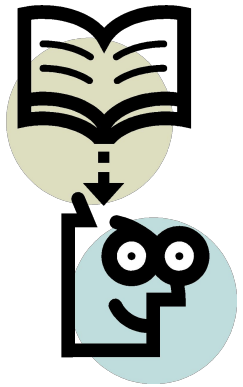
Preclinical Testing

- Laboratory and Animal Testing is Done
- Animal models- mimic human disease
- Is compound safe(non-toxic) in living organisms ?

  Eg: Nerve Damage- Neurotoxin
- Is compound biologically active?
- If YES, file an IND Application

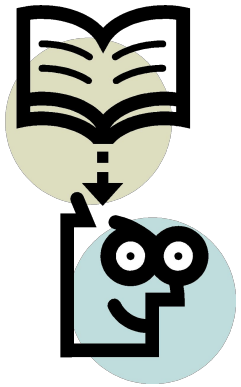
IND Application (Investigational New Drug)

- Report the results of preclinical testing
- Describes how the drug is synthesized
- Non-toxic
- If the FDA does not disapprove of the IND application within 30 days, then testing in humans can begin



NDA – New Drug Application

- If the results of all the previous testing is positive, then the pharmaceutical company files an NDA
- NDA contains all of the information gathered during preclinical to phase III
- NDA can be thousands of pages long
- Can take 2-3 years for FDA to review



Clinical Testing – Phase IV

- Once the NDA is approved and the drug is available, *post-marketing studies* are conducted to further confirm safety and efficacy during long-term use

Step involve in new drug discovery and development

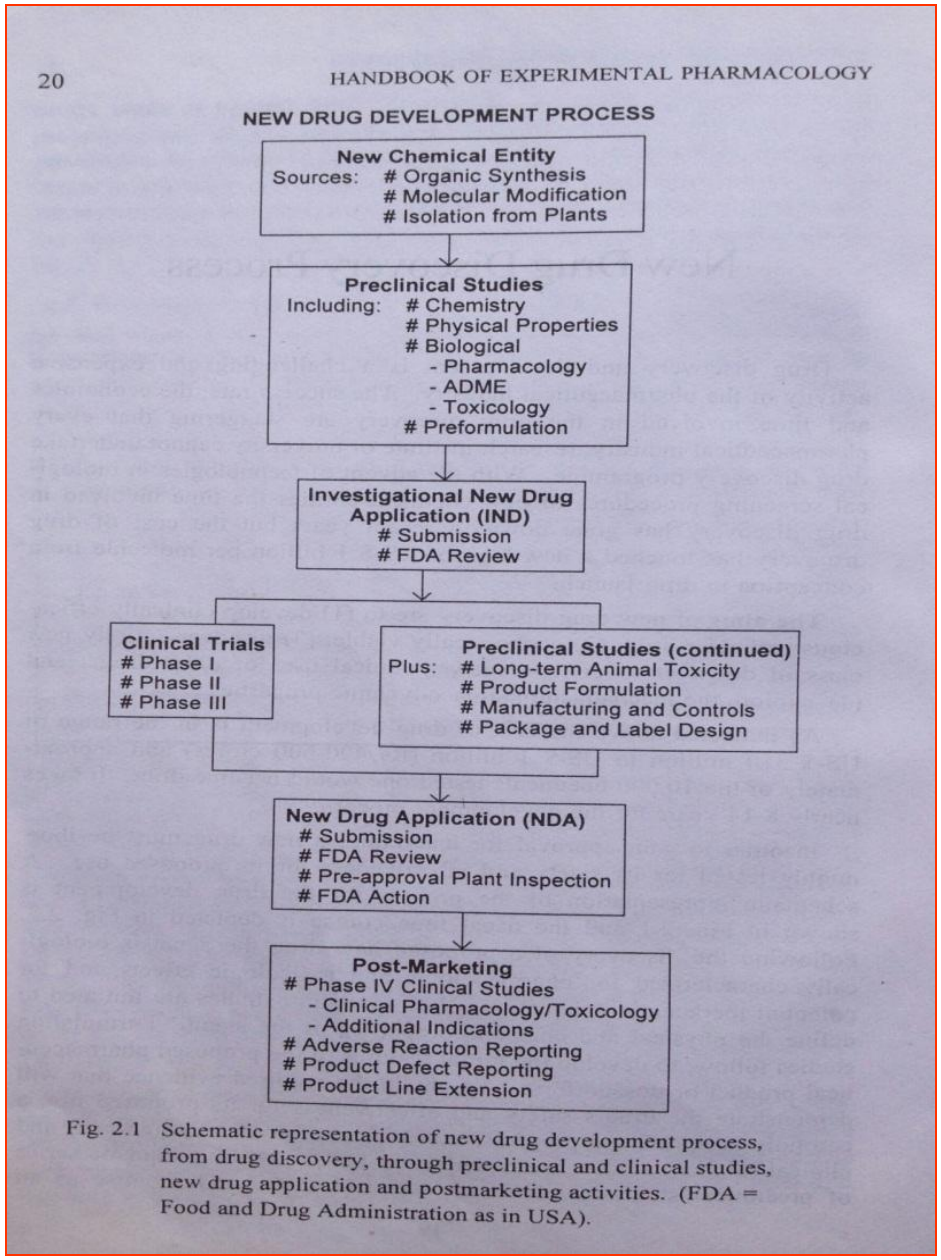


Fig. 2.1 Schematic representation of new drug development process, from drug discovery, through preclinical and clinical studies, new drug application and postmarketing activities. (FDA = Food and Drug Administration as in USA).

Thank You