

# Clinical Pharmacology and Drug Development

## Drug Development and Discovery



Module 2 Topic 1

# Pharmacology

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- **Pharmacology** is a science that deals with the *origin, nature, chemistry, effects, and uses* of drugs
- **‘Drug’** - any medicinal substance that can cure or prevent disease, relieve symptoms, and provide other benefits



# Drug Discovery/Development Process

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- Sources of Drugs
  - Plants
  - Animals
  - Synthetic



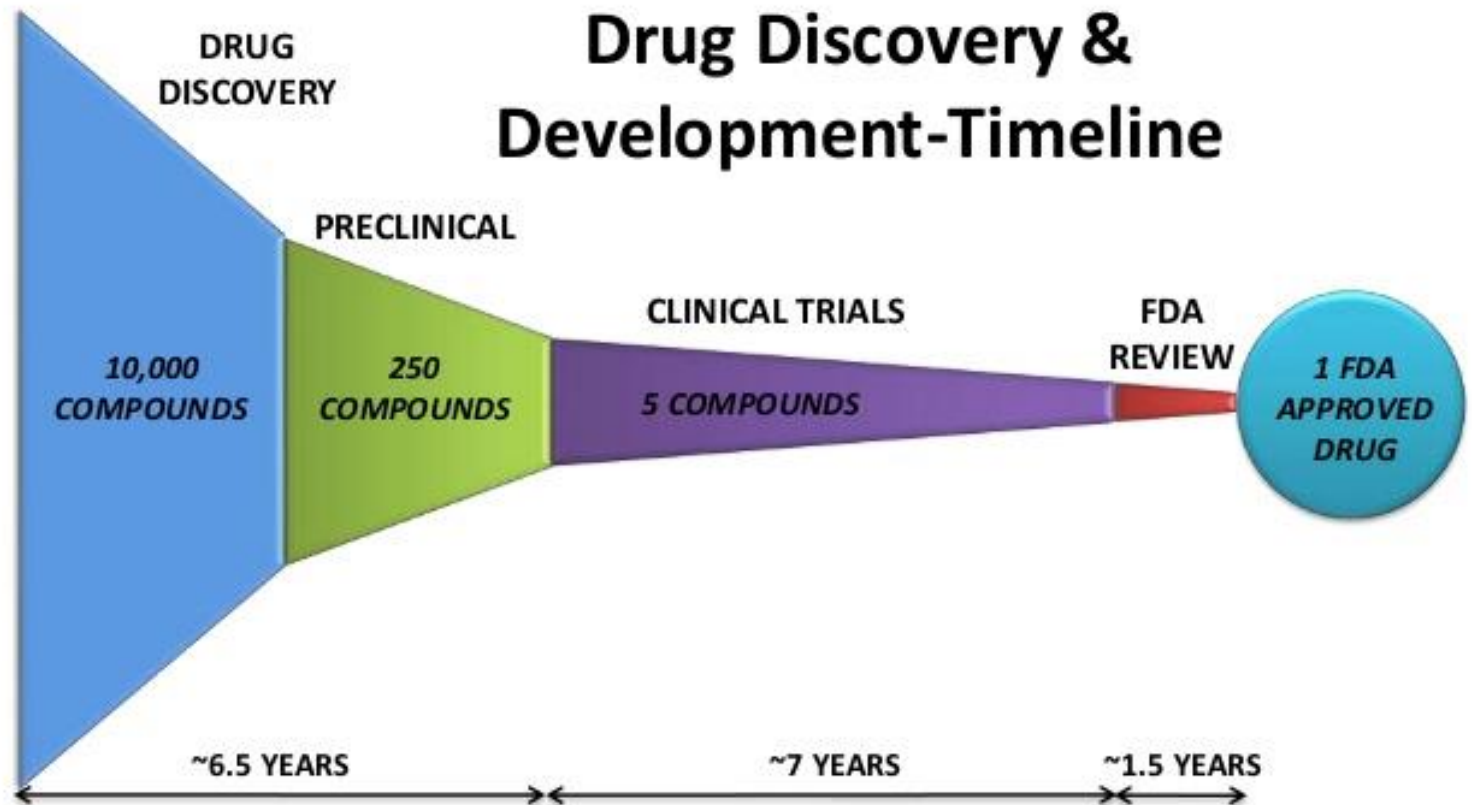
# Drug Discovery/Development Process

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- **Discovery, refinement, chemical & biological characterization**
- **Safety & toxicity in animals**
- **Formulation development**
- **Volunteer studies**
- **Patient studies**
- **Regulatory approval**
- **Marketing**
- **Post marketing surveillance**



# Drug Discovery/Development Process



# Drug Discovery/Development Process

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## **Preclinical stage:**

Evaluation of drug's pharmacological and toxic effects through in vitro and in vivo laboratory animal testing

- **Pharmacological Evaluation**

- Effects of the drug i.e. Pharmacodynamics
- Pharmacokinetics i.e. absorption/ distribution/ metabolism/ excretion (ADME); identification of metabolites, bioavailability, principal route of admin and excretion

- **Toxicological Evaluation**

- Acute toxicity studies
- Subacute toxicity studies
- Chronic toxicity studies



# Drug Discovery/Development Process

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## Clinical trials:

- Set of procedures in medical research and drug development to study the safety and efficacy of new drug
- Essential to get marketing approval from regulatory authorities
- May require up to 7 years



# Drug Discovery/Development Process

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## Clinical Stages

- **Phase 0** - Microdosing
- **Phase I** - Human Pharmacology  
(Healthy volunteers - 20 to 50 subjects)
- **Phase II** - Therapeutic Exploration  
(patients - 50 to 400)
- **Phase III** – Therapeutic Confirmation  
(large scale multi-center; 250-1000)
- **Phase IV** - Therapeutic Use  
(post-marketing surveillance)

