

Drug Discovery & Development

Dr. Rajesh Choudhary
M. Pharm. (Pharmacology), Ph. D.
Associate Professor
Shri Shankaracharya College of
Pharmaceutical Sciences, Bhilai, C.G.





How a **Drug** is discovered ??

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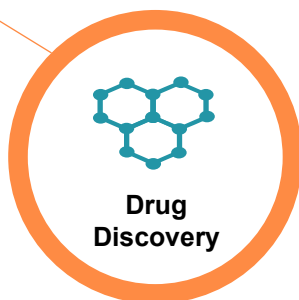
Drug Discovery Stage 1

"To discover a effective medicine, select a proper target & lead"



Systemic planning a project to discover a new drug from a unknow or known sources.

- Novel drugs
- Me too version



Target Selection

Select a Defined Target Proteins: Receptors, Enzymes, Ion Channels



Lead Findings

Selection and Finding of Lead compounds: Synthetic/Natural products



Lead Optimization

Optimize the lead activity on selected target protein: selectivity, metabolic stability, potency

Drug Discovery Stage 2

"Animals have right to good life, So conduct experiments with Proper Ethics"

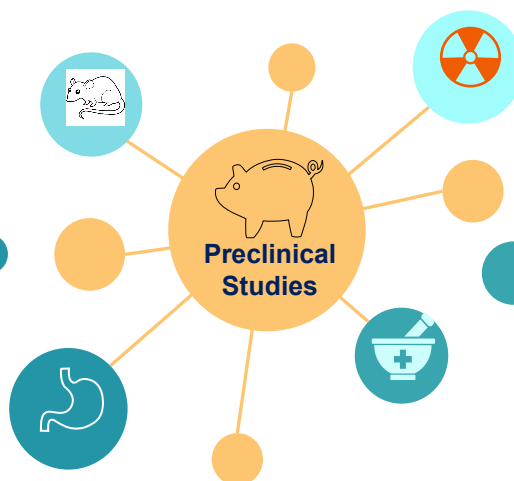


Pharmacological Testing

Check the **therapeutic** and **acute side effects** of selected **lead** for safety pharmacology

Pharmacokinetic Profiling

Study of the absorption, distribution, metabolism, and excretion of the selected lead compound



Toxicological Testing

Check the **Toxicity** profile of selected **lead**

Pharmaceutical Developments

Pre-formulation and formulation development.

Regulatory Bodies for Preclinical Studies (India)



- **Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), Government of India:** Provides Institutional Approval
- **Institutional Animal Ethics Committee (IAEC):** Provides Approval of Experimental Protocol



IND Application



- ✓ Promising lead need to IND application
- ✓ Filing the application of Investigational New Drug (IND) to Food & Drug Administration (FDA) to conduct Clinical testing on human being





Drug Discovery Stage 3: Clinical Trial



Phase I

Safety
Evaluation



Phase II

Efficacy
Evaluation



Phase III

Efficacy &
Safety

Drug Discovery Stage 3: Clinical Trial

Clinical trial conduct according to the guideline of
ICMR-Central Ethics Committee on Human Research (CECHR)

Phase 0 (Micro/Pilot Phase)	Phase I	Phase II	Phase III	Phase IV (Pharmacovigilance)
<ul style="list-style-type: none"> ➤ 10-15 healthy voluntary ➤ To understand the drug response in human being ➤ Administered at sub-therapeutic dose ➤ For Novel drug 	<ul style="list-style-type: none"> ➤ 10-100 healthy voluntary ➤ Safety evaluation ➤ Pharmacokinetic study ➤ Pharmacodynamic study ➤ Side effects 	<ul style="list-style-type: none"> ➤ 100-300 patients ➤ Efficacy evaluation ➤ Assessment of dosing requirements ➤ Long term toxicity 	<ul style="list-style-type: none"> ➤ 1000+ patients ➤ Efficacy & Safety evaluation ➤ Comparative study with standard (Therapeutic & Side effects) 	<ul style="list-style-type: none"> ➤ Post marketing Surveillance ➤ ADR reporting & ➤ Assess the Risk/Benefit ratio of a products



Drug Discovery Stage 4 Approval

NDA Application

- ✓ Promising lead need to NDA application
- ✓ Filing the application of New Drug Application (NDA) to FDA to marketing of the new drug



Drug Discovery Era

- ✓ 10th Century: Coffee
- ✓ 1803-05: Morphine
- ✓ 1877: Paracetamol
- ✓ 1901: Adrenaline
- ✓ 1912: Vit. C
- ✓ 1921: Insulin
- ✓ 1928: Penicillin
- ✓ 1961: Ibuprofen
- ✓ 2001: Etoricoxib



 /pharmacologyconceptsbyrajeshchoudhary

Thank You

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