

# General principle of preclinical trails



## ● Content ●

1. Introduction
  2. Types of Screening
  3. Preclinical Studies and its methods
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# 1. Introduction

- A laboratory test of a new drug or a series of chemicals, usually done on animal subjects, to see if they hoped for treatment really works and if it is safe to test on humans.

- **Drugs are Screened to:**

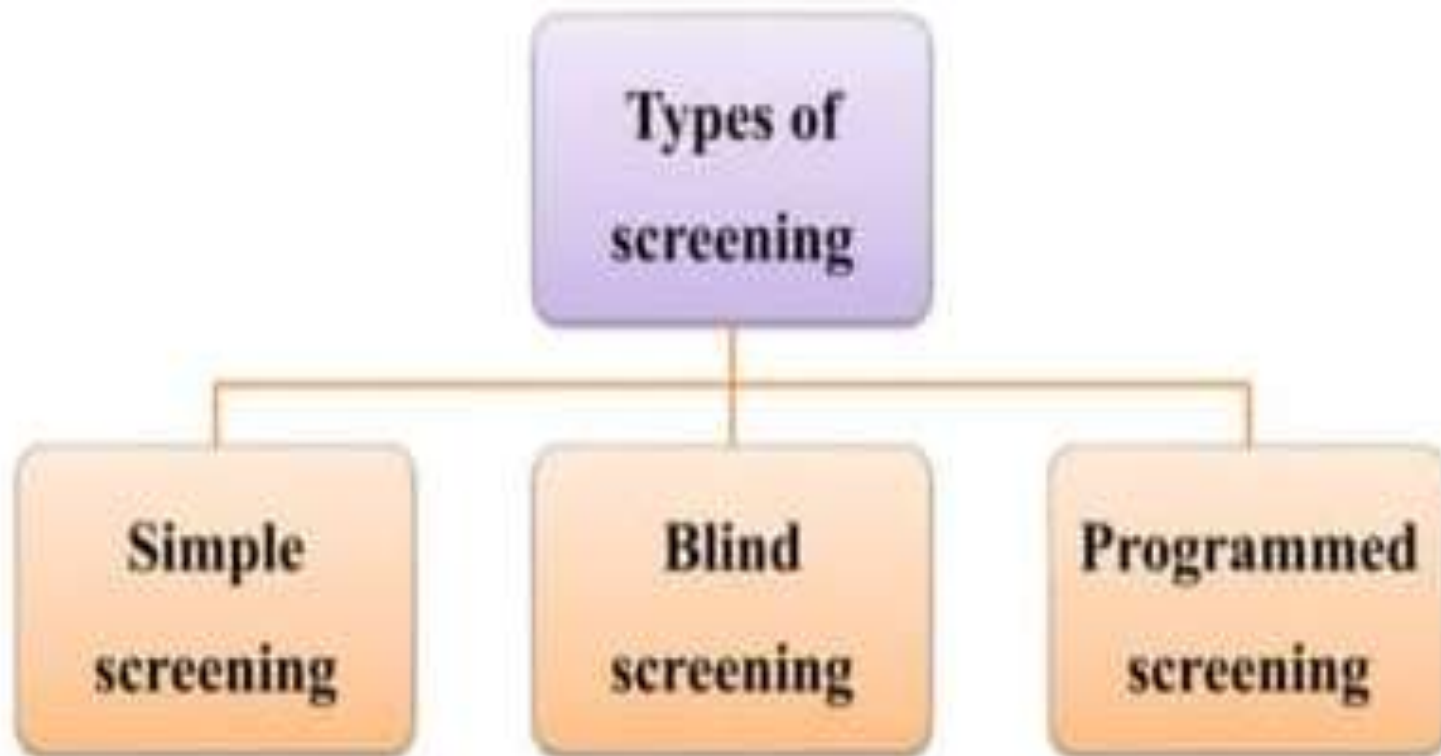
- ✓ Get Pharmacological activity of new/ chemically undefined substances.
- ✓ Investigate the functions of endogenous mediators
- ✓ Measure/ define the toxicity and/or unwanted action.

# Steps of preclinical trails

- **Several steps in preclinical trials:**



## 2. Types of Screening



## 1. Simple Screening:

- One or 2 similar test to find substances having a particular property.
- To find the substance are active in a single way.
- No need for battery/series of test.
- Inexpensive & less time consuming.
- Select only suitable method.
- Not sufficiently accrue in result.
- Eg: Hypoglycemic testing: Ability of a compound to diminish the blood glucose levels.

## **2. Blind Screening:**

- Only for the series of new chemical substance with no prior pharmacological history.
- New chemicals entity or isolated naturals.
- Provide a road towards fields of activity if they exist.
- Point out the most potent chemical with interesting pharmacological activity.
- Toxicological pathway is essential for every library of compounds.

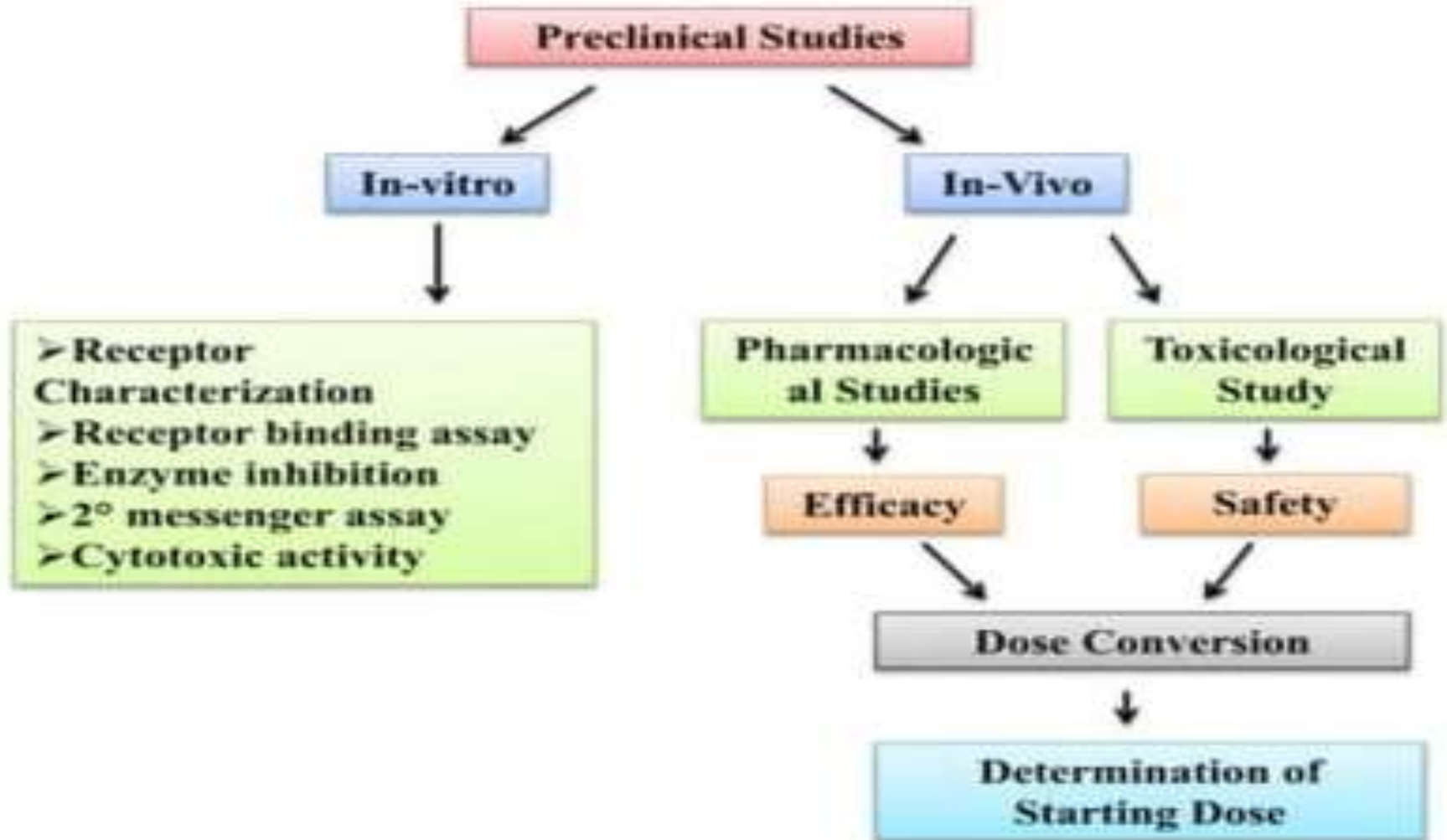
### 3. Programmed Screening:

- Provide information “what compounds are active in what ways?”.
- A new drug of specific type (known) and/or series of chemicals is to be investigated for some particular pharmacological activity. eg: System or organ specific.
- A series of testing program is required to provide information on the compounds on specific targets.
- Explores main activity and subsidiary activity .
- Potency can be compared with known compounds which lead the investigator to proceed or to terminate.
- More limited than blind, precision is expected.





## 2. Preclinical Studies and its methods



# Methods Of Screening

## In-vitro Method

- Experimental process in a given procedure which is mainly done outside the body in a controlled condition.
- Activity (Screening the activity).
- Bioassay (Define the molecular mechanism).
- Toxicity assay (Toxicity of chemicals)

## Types

- Biological assay using isolated tissue/organ.  
(skeletal/smooth muscles, aorta, heart etc.,)
- Cell culture studies:
  - Toxicity(cyto) assays
  - Immunological assays
  - Cancer cell line studies

- Chemical Assay using reagents:
  - Antioxidant assays
  - Xanthine oxidase
  - Antiglycation activity

### **Ex-vivo:**

- DNA : Protein, immunological assay
- Experimental process which is performed outside the living body in an 'artificial in-vivo environment'
- This usually lasting up to 24 hrs.
- Experimental process which is performed in the living body using laboratory animals

### **In-silico:**

- Process which is performed on computer or via computer simulator