

Summary of (10 -20) L new drug

In animals	Pre-clinical study
<ul style="list-style-type: none"> Pharmacokinetic studies • Pharmacodynamic • Dose, preparation & routes of administration • 	<ul style="list-style-type: none"> General pharmacology •
<ul style="list-style-type: none"> Acute toxicity • ■Special toxicity studies: <i>Reproductive system</i> <i>Mutagenesis oncogenesis /teratogenicity in fetus</i> 	B. Toxicological studies

Safety and efficacy	Aim	Volunteers	Clinical study Humans /clinical trails center /hospital need * supervision
Tolerability, efficacy & safety (associated adverse effects)	Study of the general - pharmacology of drug	50-20 • Healthy •	human -1 pharmacology
Establish safety of drugs	General pharmacology of - drug Assess potential - ,therapeutic effects comparison with placebo	300-50 • Patients •	2- therapeutic exploration
Short term efficacy & safety	comparison with existing - drugs By Randomized control trials	1000-250 • Multi -center • comparative patients	therapeutic -3 confirmation
Long term efficacy & safety	-to look for possible long term effects of drugs	10,000-2000 • Post - • authorization /marketing	therapeutic use -4