

Phases of Clinical Drug Development

	I	IIa	IIb	III	FDA	IV
Subjects	Healthy Normals	First time in Patients	Patients	Patients		Patients
Number	20 - 100	25 - 75	50 - 200	>300		>1,000
Measures	Asc. Dose, Kinetics, Equivalence Safety	Dose range MOA Efficacy, Safety	Efficacy, Safety	Efficacy, Safety		Efficacy, Safety, New uses
Value	Kinetics, Dynamics	Proof of Concept	Confirm mechanism of action	Confirm usefulness	Review Approve or disapprove	Surveillance, extend patent expand market
Where	In-House (controlled)	In-House (controlled)	Ambulatory	Ambulatory		Ambulatory
Time (Years)	1 - 1.5	1	1 - 1.5	3 - 6	2 - 3	1 - 2