

# Phases of Clinical Drug Development

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