

The Clinical Development Cycle

Study Phase	Number of Research Subjects	Duration	Primary Purpose
Phase I	20-100 healthy subjects	Up to 1 year	Safety
Phase II	Up to several hundred subjects	1-2 years	Safety & Efficacy
Phase III	Several hundred to several thousand subjects	2-4 years	Efficacy & Cost Benefits
Phase IV (Post Marketing)	Several hundred to several thousand subjects	2-10 years	Cost Benefits & Outcomes