

Clinical Trials
Information at a Glance

Clinical Trial Phases	Study Participants	Length of Study	Purpose	Other info...
Pre-clinical	In vitro/in vivo, animals	--	Dosing and toxicity	--
Investigational New Drug Application to the FDA				
Phase 1	20-100 healthy people with the disease	Several months	To learn about safety, side effects, and dosage	Approx. 70% of drugs move to next phase
Phase 2	Up to several hundred people with the disease	Several months to 2 years	To learn about effectiveness and further study safety	Approx. 33% of drugs move to next phase
Phase 3	300-3000 people with the disease	1 to 4 years	To continue to monitor effectiveness, side effects, and safety; to monitor of adverse reactions; to compare to other treatments	Approx. 25-30% of drugs move to next phase
Phase 4	Several thousand people with the disease	--	To continue to monitor safety; to track benefits and optimal use	After FDA approval

Information gathered from this [FDA website](#) and this [NIH website](#)