

The Drug Discovery, Development and Approval Process

It takes 12-15 years on average for an experimental drug to travel from the lab to the U.S. patients. Only five in 5,000 compounds that enter preclinical testing make it to human testing. One of these five tested in people is approved.

Discovery / Preclinical Testing	
Years	6.5
Test Population	Laboratory & animal studies
Purpose	Assess safety, biological activity & formulations
Success Rate	5,000 compounds evaluated

Phase I	Phase II	Phase III
1.5	2	3.5
20 - 100 healthy volunteers	100 - 500 patient volunteers	1000 - 5,000 patient volunteers
Determine safety & dosage	Evaluate effectiveness & look for side effects	Confirm effectiveness, monitor adverse reactions from long-term use
5 enter trials		

FDA	Phase IV	
1.5	15 total	
Review and approval process		Additional post marketing testing required by the FDA
		1 approved

Source: Pharmaceutical Research and Manufacturers of America, www.phrma.com