

The Drug Discovery, Development and Approval Process

It can take up to **15 years** for a drug to be approved.

Special designations can speed up the process

**Discovery /
Preclinical Testing**

Phase 1

Phase 2

Phase 3

FDA

Phase 4

Years	6.5	File IND* at FDA	1.5	2	3.5	File NDA** at FDA	1.5	Evaluating the drug safety over time in real-life settings
Test population	Laboratory and animal studies		20 to 100 healthy volunteers	100 to 500 patient volunteers	1000 to 5000 patient volunteers		Review and approval process	
Purpose	Assess safety, biological activity and formulations		Determine safety and dosage	Evaluate effectiveness, look for side effects	Confirm effectiveness, monitor adverse reactions from long-term use			
Success Rate	5,000 compounds evaluated		5 compounds proceed to enter trials					1 drug approved

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

*Application to start testing in human populations

**Application to make new drug available to the public

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