





The four phases of clinical trials

Clinical trials are research studies that test new treatments before they are approved for people to use. The Food and Drug Administration (FDA) is the U.S. government agency that decides if new treatments or medical devices are safe and work well for people to use. Before the FDA can approve a new treatment for use in people, clinical trial results must show the treatment works and does not cause harm to people.

Most new treatments move through four phases of clinical trials. Each phase has different goals to make sure the treatment is safe and works well to treat a disease:

 Phase	 Length of time	 Number of participants	 Goals of the phase
Phase 1	Less than one year	20 to 100 participants who may be healthy or have the disease	<ul style="list-style-type: none"> Learn how the treatment works in the human body Understand the best dose (amount) of the treatment
Phase 2	A few months to 2 years	About 300 participants who have the disease	<ul style="list-style-type: none"> Learn more about how safe the treatment is for people to use
Phase 3	1-3 years	300 to 3,000 participants who have the disease	<ul style="list-style-type: none"> Learn if the treatment works to prevent, diagnose or treat the disease Learn more about safety and possible side effects
Phase 4	Many years	Thousands of participants who have the disease	After the FDA approves the treatment for use with the public, researchers continue to look at: <ul style="list-style-type: none"> The treatment's benefits Side effects The best way to use it

Learn more at [KidneyFund.org/clinical-trials](https://www.kidneyfund.org/clinical-trials)