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:

<table>
<thead>
<tr>
<th>Phase</th>
<th>Length of time</th>
<th>Number of participants</th>
<th>Goals of the phase</th>
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| Phase 1 | Less than one year | 20 to 100 participants who may be healthy or have the disease | • 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 | • 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 | • 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:  
• The treatment’s benefits  
• Side effects  
• The best way to use it |

Learn more at KidneyFund.org/clinical-trials