

CLINICAL TRIAL RESEARCH PHASES

PHASE

1

Phase 1 of an experimental drug study involves evaluating the drug's safety before it advances to further clinical studies. A new drug candidate is typically tested on a small group of healthy research participant volunteers. Information about side effects is recorded to determine if the drug should move to Phase 2.

Phase 1 usually takes several months and involves 20-80 people.



MASSACHUSETTS
Alzheimer's Disease
Research Center



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PHASE

2

In Phase 2, researchers administer the experimental drug to a group of patients who have the disease or condition for which the drug is being developed. Several doses of the drug may be tested to determine which dose is the safest. Phase 2 usually does not involve testing whether the drug is effective in treating the disease, but sometimes tests are administered to see if the drug might be effective in the future.

Phase 2 typically lasts up to two years and involves several hundred people.



CLINICAL TRIAL RESEARCH PHASES

PHASE

3

In Phase 3, researchers compare the safety and effectiveness of the experimental drug to the current standard treatment. Study participants are usually randomized, meaning some participants get the new drug and others get a placebo, or a sugar pill.

This phase typically involves 1,000 – 3,000 participants and lasts from 1 – 4 years.



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PHASE 4

Following Phase 3, the new drug moves to the Federal Drug Administration (FDA) for approval. Once approved it advances to Phase 4 Clinical Trial/Post-Market Surveillance.

The FDA monitors the drug for safety and potential adverse effects.

