



CLINICAL TRIALS

Fact Sheet 003



Clinical trial phases

Clinical trials are separated into different phases. Not every drug goes through a phase 0 trial and not every drug goes through a phase 4 trial, but all drugs go through phase 1, 2, and 3 trials

Phase 0 clinical trials

In some situations, before we do a phase 1 trial, we may elect to do a phase 0 trial.

Phase 0 trials are trials that are conducted in a small subset of patients, usually around 5 to 15 patients. Phase 0 help us understand how a drug is metabolised or whether the drug does what we want it to do in human beings.



Phase 1 clinical trials

A phase 1 clinical trial is the first stage of clinical testing in volunteers after laboratory research. The purpose of a phase 1 clinical trial is to determine the answer to three questions. Is the treatment safe? Are there any side effects? Does the treatment work better than current treatment?

Volunteers for phase 1 trials are the first to try new and innovative treatments. Phase 1 trials typically involve a small number of participants, usually 15 to 100 volunteers. Participants are divided into small groups that are called cohorts. The first cohort receives a low dose of the new treatment. After the first dosage, treatment is adjusted from there. The dose increases until the trial investigators find the most effective and safe dose for future testing. With each increasing dose, doctors test each volunteer to see how well the volunteers are responding.

Clinical trial phases

Not every drug will go through phase 0 trials. The drugs that do go through a phase 0 trial usually have small sample size, low dose of the drug and a single or few exposures to the drug to try and gauge preliminary information that can be used to design future trials.



Phase 2 clinical trials

A phase 2 clinical trial is the second stage of human clinical trials. The purpose of a phase 2 clinical trial is to determine how well the new treatment works, how the treatment affects a larger group, how much of the drug should be given to be most effective, and what types of diseases the treatment can treat.

Normally, phase 2 studies are performed in a large group of volunteers ranging from about 50 to 300 people. Phase 2 studies are sometimes divided into phase 2A and phase 2B.

A phase 2A trial is designed to determine the best and most effective dose that should be given. A phase 2B trial is designed to study how well the treatment works at the prescribed doses. The goal of a phase 2 clinical trial is to determine if the treatment is as effective as or more effective than current treatments. If it is, then the treatment will move to phase 3.

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Phase 3 clinical trials

A phase 3 clinical trial is the third phase of human clinical trials. These trials compare new treatments with the best current available treatment. Normally, phase 3 clinical trials are performed in a larger group of volunteers ranging from about 300 to over 3,000 people. These studies can be run in many different countries all over the world. Only about 18% of phase 2 trials make it to phase 3, meaning the new treatment is quite effective.

The goal of a phase 3 clinical trial is to determine the effectiveness of the new treatment measures against the effectiveness of current treatments. A phase 3 clinical trial might also look into new doses or ways to administer existing therapies. If the treatment is effective, then the new treatment or new medication can be presented to the government for approval.

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Phase 4 clinical trials

After a phase 3 trial is complete and the drug is approved and available as a treatment option, we sometimes elect to do phase 4 trials. These are large trials where data is collected to monitor rare events or rare side effects of the drug.

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ext fact sheet in series: [Risks & benefits of clinical trials](#)