

What is Clinical Research?

Clinical research is how researchers learn about new medicines that could help people feel better and live longer.¹ Clinical research looks at how treatments, therapies, and medical care impact people's health. **Clinical trials** are research studies that test whether new medicines, treatments, medical devices, or ways of providing care are safe and work well on the volunteers who try them.

Clinical Trials Ask Two Questions:

- *Does the treatment work?*
- *Is the treatment safe for most people to use?*

How Research Can Lead to Clinical Trials

Research is the process of collecting information that researchers need to start a clinical trial. Research also shows the reasons why a clinical trial is needed, like:



Why does one group of people have certain illnesses or health conditions?



Has this treatment been used by other people before?



What is the treatment?



Why is this treatment better than another one?²



How can the treatment help people?

Every medicine, vaccine, and medical test must go through clinical trials to make sure it is safe, works well, and meets quality standards, and then the U.S. Food and Drug Administration (FDA) can decide to approve it for use.

How Research Can Lead to Clinical Trials



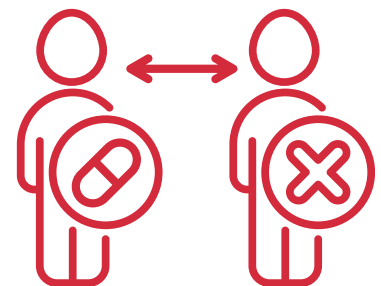
Clinical trials have several phases that help researchers know if a drug is safe and if it does what it says it can do. The number of people in each phase expands as the researchers learn more about the drug and understand any risks or complications that might come with taking the drug.

The first phase of a clinical trial begins with a small number of people to see if the medicine is safe and if they are getting the right amount of medicine.

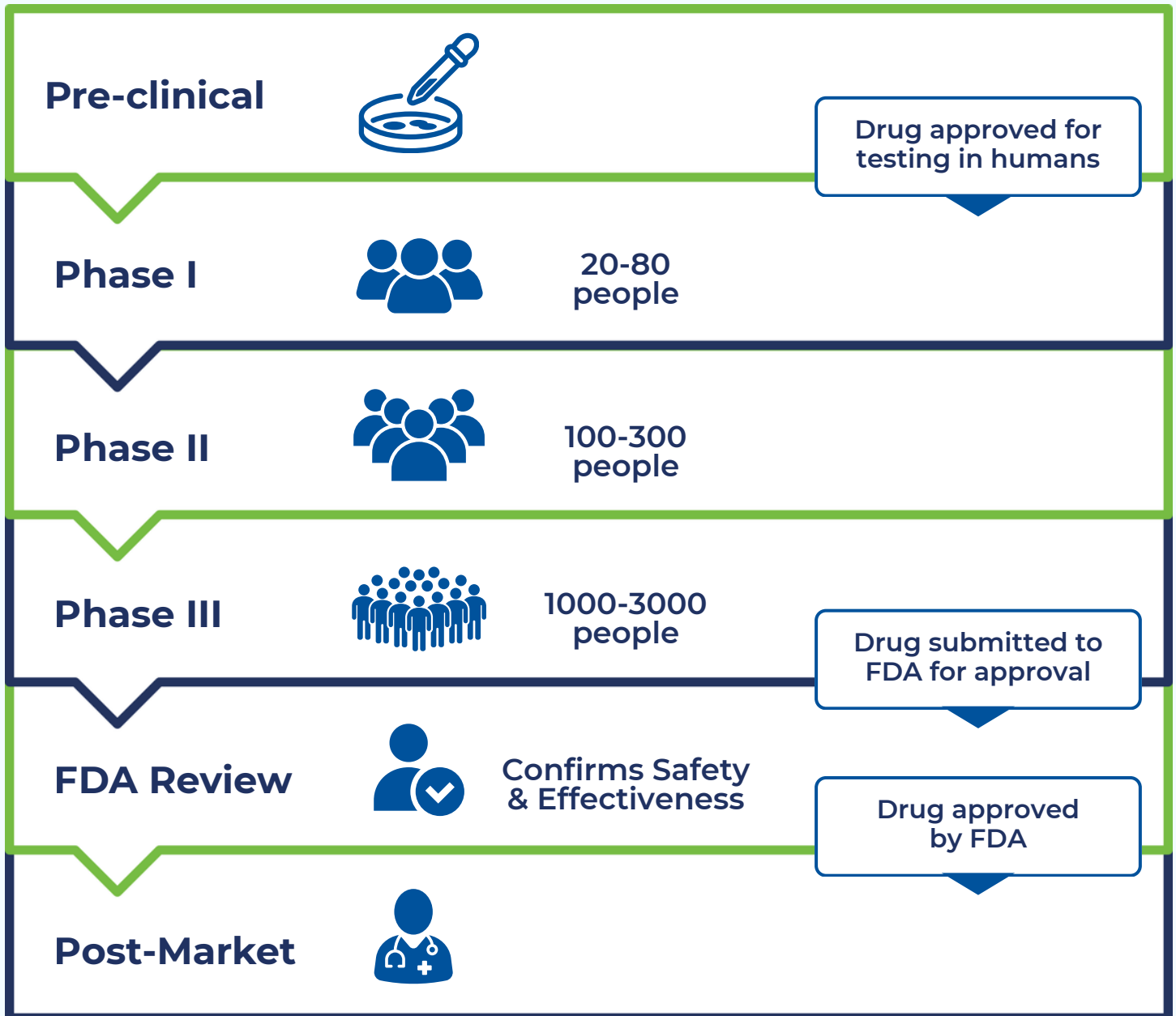
With each phase of the clinical trial, the group of people in it gets bigger so researchers can test how well the drug works and if the benefits of the treatment are greater than the risks that might exist with taking a medicine.

They may also look to see if the drug works better than another drug that is already being used.²

Sometimes, one group of people in the clinical trial gets the medicine, and another group gets something called a placebo. A **placebo** looks like real medicine, but it does not have any medicine in it.² This helps researchers know if taking the medicine works better than not taking any medicine without the people in the study knowing if they are taking the medicine or not.



Phases of Clinical Trials



Why is it important to participate in clinical trials?

Clinical trials are how we get our next generation of treatments and cures. Clinical trials help us see if interventions that work in the lab are safe and do what they say they're going to do.

Just like the people who helped find treatments for things like congenital heart disease by being a part of clinical trials, you too can be part of helping find the next generation of treatments for people with Down syndrome!

References

- ¹ John Hopkins Medicine. Clinical Research: What Is It? www.hopkinsmedicine.org. Published 2024. <https://www.hopkinsmedicine.org/research/understanding-clinical-trials/clinical-research-what-is-it>
- ² NIH. The Basics National Institute on Aging. Published April 24, 2025. <https://www.nih.gov/health-information/nih-clinical-research-trials-you/basics>