

# Do You Have What It Takes to Join a Phase 1 Clinical Trial?

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“Life's most persistent and urgent question is: What are you doing for others?” ~ Martin Luther King, Jr.

For some, volunteering at their local food bank is a preferred way to give back. Some donate money to organizations or non-profits they believe in. Others donate blood. But there is another way people can give back that may not be as top of mind: Participating in clinical trials.

Clinical trials are critical to the progression of medical research and they rely on people who are willing to devote themselves, their time, and their energy in the name of science. Clinical trials wouldn't be possible without people volunteering to participate during all three crucial phases of testing. Phase 1 clinical trials typically focus on healthy participants in order to first determine whether medicines and vaccines are safe for use in patients and whether there are any side effects.<sup>1</sup> However, certain Phase 1 trials (such as oncology) focus on patients rather than healthy volunteers. Later on, in Phases 2 and 3, the study drug is tested to further determine the study drug's safety and how well it works (efficacy) in patients with a specific medical condition or disease.

Clinical trials may be sponsored by one of a several kinds of entities, including hospitals or medical centers, government agencies, and pharmaceutical companies. Some research studies take place within a dedicated clinical research facility, such as the Pfizer Clinical Research Unit (PCRU) in New Haven, Conn.

Jennifer Long, head of Global Clinical Operations at the PCRU, says that participants are "crucial to the success of Phase 1 clinical trials."

"We see a mix of volunteers," she says, "but they are usually very motivated individuals who have a desire to be part of something that supports the progression of clinical research and the prospect of doing good for others."

Simply put, without healthy participants, science would not be able to help sick people who need the development of these potential medicines and treatments the most.

Participating in a Phase 1 clinical trial is a personal decision, and one that might instill a sense of greater purpose. If you're interested in getting involved, here's what it takes:

### **Are you in good overall health?**

According to Amanda Dunlap, a Clinical Research Communications Specialist at the PCRU in New Haven, working with healthy participants—typically adults 18 to 55 years old—allows researchers to assess a drug's safety and potential side effects during Phase 1 before it is given to those with the medical condition that is being studied.

When a person is interested in enrolling in a Phase 1 trial, they will go through a medical screening process, which will also look at their personal medical history. "The screenings are a little different depending on the specific study, but for the most part, it is similar to what you might get at an annual checkup at a doctor's office," says Dunlap. "Some studies may involve blood tests or electrocardiograms to look at a person's heart, for example., so we have baseline assessments to compare throughout the study."

### **Do you meet the eligibility criteria?**

The main eligibility criteria include sex, age, weight, and medical history.<sup>2</sup> Additionally, a set of specific reproductive criteria may apply depending on the study design or drug being tested. As part of the steps to join a clinical trial, the study doctor will confirm whether you meet all eligibility criteria and are able to participate.

"Throughout the screening process, participants are provided with a lot of background information about the study—how long it will last, what is involved, and what is expected in terms of participation in the trial," says Long. "At Pfizer, we are committed to protecting the people who take part in our clinical trials, and to upholding the highest ethical standards as we seek safe and effective ways to prevent or treat diseases. The PCRU staff is there to support our study volunteers every step of the way."

### **Do you agree to participate in the study through informed consent?**

Before joining a Phase 1 clinical trial, the study team will review the details of the study with you, including possible risks and benefits, so you will know what to expect. If you decide to participate, you will be asked to sign an informed consent document. This document outlines your rights as a participant as well as details about the study, including the study medicines, procedures, and tests, possible risks and discomforts, the schedule of the study activities, and the length of the study. This is the time for you to discuss any questions or concerns with your regular medical provider to better understand how the study might impact your health and also to ask any

questions of the study doctor and the research staff before you decide to join. Taking part in a clinical trial is entirely voluntary and you may leave at any time.<sup>2</sup>

## **Do you have the time?**

Phase 1 clinical trials in healthy participants can last anywhere from several days to months.<sup>3</sup> Because participants are typically closely monitored, people sometimes stay at the clinic where the trial is being held.

Trial participants may need to take time off from work or make arrangements with families to be away for a period of time. “A lot of participants that come to the PCRU have seasonal gaps in work,” says Long. “Then there are those who, from an altruistic perspective, just want to give back.”

In most cases, volunteers must be willing to travel to the clinic in order to take part in the trial; a cost that is often included in their overall study compensation or is reimbursed. At the PCRU, when they are not completing study procedures, people can join activities or enjoy free time however they choose. “It isn't just sitting in a hospital bed for 12 days,” adds Dunlap, debunking a common misconception.

## **So, do you have what it takes?**

If you're in good health, meet the eligibility criteria, agree to participate through informed consent, and have the time, the information gathered with your help could make a huge difference in others' lives, especially if you are a [member of an underrepresented group](#).

Both Dunlap and Long encourage more people to consider becoming a volunteer, noting that there are clinical trials happening all over the world at any given time.<sup>4</sup>

“It's really important for potential participants to know that their participation does make a difference and it does have an impact on what we're ultimately able to do for patients,” says Dunlap. “It's the first step in helping us find new treatments, therapies, and cures for people who have various diseases.”

“Volunteers make our research possible,” adds Long. “Healthy volunteers who are committed and dedicated are critical to our work in the development of safe medications that can go on to save lives.”

Visit Pfizer's clinical trials website to learn more about [how to become a Phase 1 clinical trial participant](#).

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Sources:

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4. ClinicalTrials.gov. Available at: <https://clinicaltrials.gov/>. Accessed 4/22/21.

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