WHAT IS A CLINICAL TRIAL?

Clinical trials are investigations of specific treatments or protocols for a particular health condition or symptom. Volunteers with the health condition receive the treatment and report side effects and outcomes as a part of the process to approve the new treatment and make it available to everyone.
TYPES OF CLINICAL TRIALS

Traditional Clinical Trials
- Centralized location
- In-person screenings and visits
- Smaller pool of available participants

Decentralized Clinical Trials
- Fully or mostly remote
- Telehealth screenings and follow-ups; greater use of technology
- Treatments may be mailed or brought to the home
- More accessible for patients with pain

Hybrid Clinical Trials
- Combination of in-person and remote aspects
- Initial screening may be in person, but follow-ups may be remote
- Offers more flexibility

Observational Trials
Track symptoms and outcomes without incorporating a new treatment — for instance, to assess a need.

Interventional Trials
Test potential new treatments such as medications or devices as part of the process of bringing a new therapeutic to the market.
# PHASES OF CLINICAL TRIALS

## Pre-Clinical Testing
Testing on cells or animals.

## Phase 1
A small group of healthy volunteers without the condition receives the treatment and reports side effects. The study progresses only if no major problems are observed.

## Phase 2
A small group of people with the condition receives the treatment and reports side effects, as well as outcomes; effective dosage is analyzed. The study progresses only if positive outcomes, such as pain relief, are measured.

## Phase 3
A larger group of people with the condition receives the treatment and reports outcomes to show the treatment’s effectiveness for a wider variety of people. FDA approval is sought after this phase only if the treatment is determined to be as good as or better than treatments already on the market.

## Phase 4
Takes place following FDA approval to measure long-term safety of the treatment.

# BENEFITS OF PARTICIPATING IN CLINICAL TRIALS

- Receiving no-cost access to new treatments when the standard of care does not effectively treat your condition.
- Accessing potential alternatives to more invasive treatments.
- Knowing you are contributing to important research advancements that could make a difference to others living with pain.
QUESTIONS AND FACTORS TO CONSIDER

- What happens during the trial? Do I know how long the trial will last?
- Do I have comorbidities or other factors that will disqualify me from enrolling?
- Am I prepared for the time and effort commitment of adhering to a clinical trial?
- Have I considered my risk level, age, and current medications?
- Have I discussed participation in this trial with my physician?
- Am I prepared to deal with unexpected side effects?
- What are the potential related costs once I’m enrolled in a trial?

Participants in some trials will unknowingly receive a current treatment or a placebo (a therapeutic with no treatment value) rather than the new treatment being studied, but all participants will receive good care.

For some trials, participants will need to complete a “medication washout period” — not taking their current medications for a certain period of time to avoid interactions with the studied drug.

WAYS TO GET INVOLVED IN CLINICAL TRIALS

- uspainfoundation.org/pain/research
- clinicaltrials.gov
- Ask your medical providers about local study options
- Patient advocacy groups often have information about trials

There are several levels of screening to determine if someone is a good fit for a trial. Patients can sign up through some of the services listed above, in addition to local notification services, to be notified of trials that may be a good fit for them.

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