U.S. PAIN FOUNDATION

CLINICAL TRIALS 101

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.

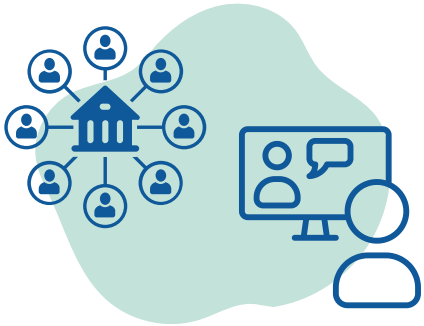
TYPES OF CLINICAL TRIALS

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.

uspainfoundation.org

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