

# Understanding Clinical Trials

## What are clinical trials?

Clinical trials are research studies that provide rigorous data about risks and benefits of therapies for people. They eliminate therapies that are ineffective or hazardous.

## Who needs clinical trials?

Doctors use clinical trial results to recommend a therapy. Government agencies and insurance companies use them to decide whether to pay for the therapy. Patients use the information to decide if they want the therapy.

## What is a clinical trial network?

A clinical trial network is a group of centers who are organized and prepared to carry out clinical trials. Many centers do not have enough patients with a given condition to carry out clinical trials rapidly; by joining forces, centers can test therapies much faster. Clinical trial networks are the most rapid and cost-efficient approach to testing therapies. They establish the mechanism to randomize thousands of patients to the most promising therapies.

## How are clinical trials done?

New treatments are usually tested in animals first to establish safety and efficacy, method, dose. Clinical trials are carried out in four phases:

**Phase 1** trials establish the safety and feasibility of the therapy.

**Phase 2** trials optimize the dose and outcome measures.

**Phase 3** trials are usually large multi-center trials that test the therapy in large numbers of patients to show treatment efficacy. The U.S. Food & Drug Administration (FDA) usually requires two positive phase 3 trials to approve a therapy.

## Who does clinical trials?

Clinicians and scientists develop the **protocol** for the trial: the treatment, patient eligibility, outcome measures, and hypotheses. Clinicians carry out clinical trials by recruiting patients, telling them about the trial and protocol, obtaining informed consent, following the protocol, collecting and analyzing data, and publishing the results and conclusions in medical journals.

## Who approves clinical trials?

All clinical trials go through several levels of approval before they can be carried out. First, the designers of the trial approve the protocol. The Institutional Review Boards (IRB) of each hospital must review and approve the protocol. The trial must be approved by the sponsor that pays for the trial, e.g. a foundation or drug company. Finally, if the trial involves a new drug, a new use of a drug, a cell transplant from another individual, or if any cells have had more than minimal manipulation, an application for Investigational New Drug (IND) must be submitted or approved by the FDA.

## How can we get a spinal cord injury clinical trial network?

### Pass The Christopher Reeve Paralysis Act and fund it with \$300 million.

CRPA has been languishing in Congress now for 5 years. We've lost precious time. We could already have established a clinical trial network with many potential treatments being tested. Let's move! Write your legislators, come to Washington, inform everybody. Together, we can do it!

\*\*Don't forget...CRPA does not request any controversial cellular type research.