Hep C Patients Considering a Hep C Clinical Trial

February 9, 2016 By Connie M. Welch

There are many reasons why Hep C patients or other patients with conditions may want to consider participating in a clinical trial. Patients may or may not have medical insurance coverage and need treatment for Hep C, or you may have been denied approval for Hep C treatment from your insurance company. Regardless of the patient's reasons, Hep C patients who participate in clinical trials are warriors on the front lines and we commend them.

Hep C treatment medications go through fine tuned phases before it's ready to go into clinical trial. CenterWatch is a credible go to clinical trial resource packed with valuable resources to inform patients seeking information about all clinical trials.

In this overview of clinical trials, CenterWatch states, "Clinical trials are conducted to collect data regarding the safety and efficacy of new drug and device development. There are several steps and stages of approval in the clinical trials process before a drug or device can be sold in the consumer market, if ever.

The first step is research. Drug and device testing begins with extensive laboratory research which can involve years of experiments in animals and human cells. If the initial laboratory research is successful, the data is sent to the FDA (Food and Drug Administration) for approval to continue research and testing in humans for clinical trials.

For more detailed information click here, U.S Food and Drug Administration: The drug development process by the FDA Steps 1 through 5.

Once approved, human clinical trials of experimental drugs and devices can begin. This is typically conducted in four phases. Each phase is considered a separate trial and, after completion of a phase, investigators are required to submit their data for approval to the FDA before continuing to the next phase. Each phase is vitally important. The FDA shares what each phase represents.

Phase 1: Researchers test a new drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.

Phase 2: The drug or treatment is given to a larger group of people to see if its effective and to further evaluate its safety.

Phase 3: The drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.

Phase 4: Studies are done after the drug or treatment has been marketed to gather information on the drug's effect in various populations and any side effects associated with long-term use.

CenterWatch states, "All clinical trials have guidelines about who can participate. Before joining a clinical trial, a volunteer must qualify for the study. The factors that allow volunteers to participate in a clinical trial are called "inclusion criteria" and the factors that disallow volunteers from participating are called "exclusion criteria."

These criteria can include age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. Other clinical trial criteria may need to be met in order to know if the volunteer's condition is what the study is looking for.

Patients who volunteer receive a physical examination and their medical history is reviewed by the clinical study physician and/or research staff member once they are enrolled in the study. The patient's health and condition will be monitored during and after the trial. Blood tests and exams will be done throughout the study. Each patient will receive a detailed description of what is expected from each patient in consent forms along with specific clinical trial information.

It is noted that volunteers may withdraw from a study at any time for any reason.

See highlighted link for more detailed information from CenterWatch on Volunteering for a Clinical Trial.

See more resources about Clinical trials for Hep C in this link:

- Clinical Trials and Research
- Hepatitis C Clinical Trials Listing

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