

• • • • • **How to Evaluate** • • • • • **a Clinical Trial**

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After a new drug is tested in laboratory settings and shows promise, it is tested on humans in a clinical trial. Today, there are dozens of clinical trials or studies that evaluate new antivirals, interferons, and innovative vaccines on patients infected with chronic hepatitis C (HCV).

Researchers recruit patients through the U.S. National Institutes of Health's Clinicaltrials.gov registry, Centerwatch.com, and through medical offices and organizations. Medical providers learn about the trials and may recommend a study to

a patient who meets the study's criteria. Medical providers participating in or leading the study may recruit their own patients. Even when medical providers are not directly involved in a study, they can refer patients and may perform testing and monitoring required by the trial and then send the results to the study's researcher.

Patients should be guaranteed that, if they end up in the placebo group, they will have access to the new drug, if it proves successful, at the end of the trial.

Every clinical trial in the United States must be approved and monitored by the researcher's Institutional Review Board (IRB) to make sure the risks to patients are as low as possible. Every participant is asked to read, understand and sign a consent form that lists the potential dangers or risks. Patients should ask questions and be actively involved in the registration process. A clinical trial coordinator will be assigned to follow participants to make sure that the patients understand their rights and are carefully monitored throughout the study.

Questions patients should ask before enrolling:

- Why is this drug better than what is currently approved for hepatitis C treatment by the U.S. Food and Drug Administration (FDA)?
- What are the possible risks, side effects, and benefits?
- If the drug is an antiviral, will it cause viral resistance or cross-resistance?
- How will the treatment affect quality of life?
- Will researchers cover the cost of the drug and doctor's visits?
- What follow-up care is required?
- What determines if the drug was successful?
- Will results of the trial be provided to participants?
- Will a specialist or a primary care provider be in charge of a patient's care?
- Is there a chance a patient could get a placebo instead of the experimental drug?

Randomized trials risks and benefits:

Participating in a randomized trial means some patients will receive a placebo (a sugar pill that provides no treatment), some will get the current conventional treatment for hepatitis C, and some will get the new, experimental drug. Before participating in a clinical trial, patients should be guaranteed that, if they end up in the placebo group, they will have access to the new drug, if it proves successful, at the end of the trial.

Different Phases of a Clinical Trial

Phase I: This is the first time a drug is tried in humans. The goals are to discover if the drug works, the safety of the drug, and what quantity or how much of the drug can be given safely.

Phase II: The drug appears promising, so now researchers will try to fine-tune its dose and evaluate its safety and effectiveness.

Phase III: The drug is compared to the current standard of treatment to see if it is superior or as effective. During this phase,

It is important for study participants to know that at any time they can withdraw from the study without any repercussions.

Getting support:

Before patients meet with a study's doctor or coordinator, it is important that they plan ahead and write down questions to ask to evaluate the study. One may ask a friend or relative to come along to hear the doctor's responses, and tape record or write down the discussion to review later. If the patient is young, bring a babysitter so parents/caregivers can speak privately, without distractions, with the doctor.

patients will often be treated with either the new drug, the current drug that is the standard of care, or a placebo.

Phase IV: The drug is studied to find out about treating sub-populations with the same condition that may not have been included in the original studies, or for the treatment of a different condition, or if there are questions that need to be answered that were not addressed in previous studies.



For more information about drugs in development to treat hepatitis C, visit our HCV Drug pipeline.

www.hcvadvocate.org/hepatitis/hepC/HCVDrugs.html

For information about current clinical trial enrollment visit:

www.clinicaltrials.gov

Helpful websites about clinical trials:

- **www.clinicaltrials.gov**
Features information about hepatitis C clinical trials in the U.S. and around the world.
- **www.centerwatch.com**
Provides clinical trials information to professionals and patients through its online database and email lists.

Visit the HCV Advocate Web Site: www.hcvadvocate.org

Below are just some of the publications and services you can find up at our site:

- *HCV Advocate* Monthly Newsletter
- Educational Materials and Fact Sheets in English, Spanish, French, Hmong, Vietnamese, Russian, Tagalog, Somali, Korean and Chinese
- Medical Writers' Circle
- *Hepatitis Journal Review*
- Disability & Benefits Column
- Hepatitis B information
- HIV/HCV Coinfection information
- Support Group Listings for USA, Canada and Elsewhere
- Physician Locator (USA)
- Links to Clinical Trials
- Links to Other Helpful Organizations
- Event Listings
- Fact Sheet Series:
 - Easy C Facts
 - Basics
 - HCSP Fact Sheets

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