



Understanding Clinical Trials

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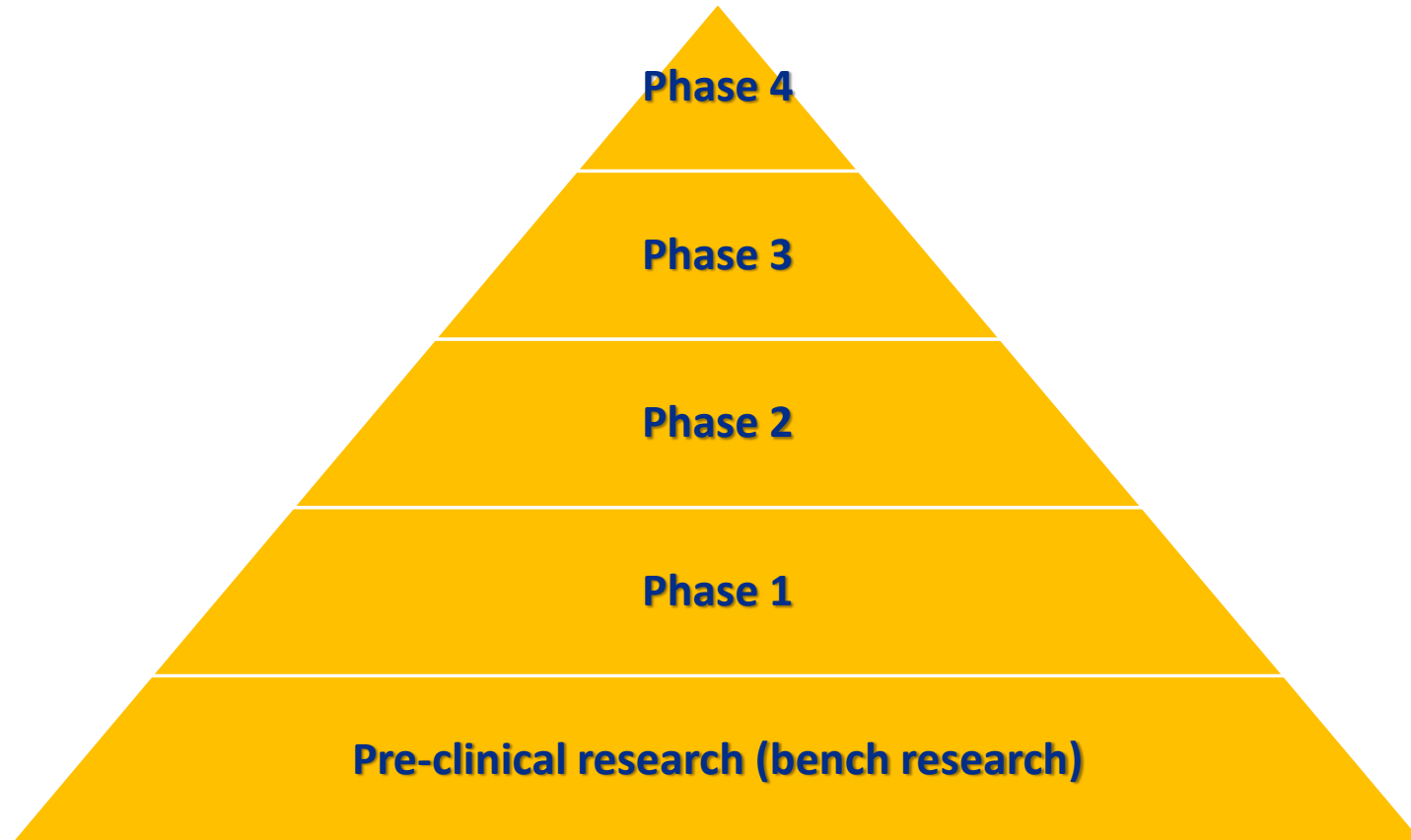
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What are Clinical Trials?

Experiment	that may be investigating a new medication, or a new combination of 2 medications that are known to work well individually for two different conditions.
Futuristic	Clinical trials are planned to be conducted “prospectively designed” with predefined objectives and protocols to reduce bias and enhance replicability “reproducibility”.
Control Group and Blinding	<ul style="list-style-type: none">- Including control groups and randomization allows isolation of intervention effects and balances confounding factors.- Blinding participants and investigators reduces expectation bias, strengthening the validity of trial results.
Highly Regulated	Ethical review boards and regulatory bodies ensure participant safety and informed consent, maintaining trial integrity and transparency.

Phases of Clinical Trials





Why Clinical Trials Matter?

Foundation of Evidence-Based Medicine

Clinical trials provide rigorous evaluation of new treatments ensuring safe and effective medical care.

Establishing Causality

Trials use protocols and controls to distinguish true treatment effects from placebo and natural progression.

Regulatory Approval Gateway

Clinical trial data is essential for drug and device approval by regulatory agencies ensuring safety and efficacy

Driving Medical Innovation

Trials challenge paradigms and generate knowledge that advances treatment strategies and medical progress

Endpoints and Outcomes: Measuring What Matters

Clinical Endpoints

Clinical endpoints measure how patients feel, function, or survive, such as survival and symptom improvement.

Surrogate “proxy” Endpoints

Surrogate endpoints are indirect measures that predict clinical benefit and can shorten trial durations.

Patient-Reported Outcomes (PROs)

PROs capture patients’ perspectives on symptoms and treatment burden, supporting patient-centered care.

Importance of Endpoint Selection

Choosing clear primary and secondary endpoints avoids bias and ensures trial results are clinically relevant.

Stakeholders and Their Roles in Clinical Trials

Participants' Central Role

Participants contribute time, accept risk, and share data, making clinical trials possible while requiring safety and respect.

Investigators and Study Teams

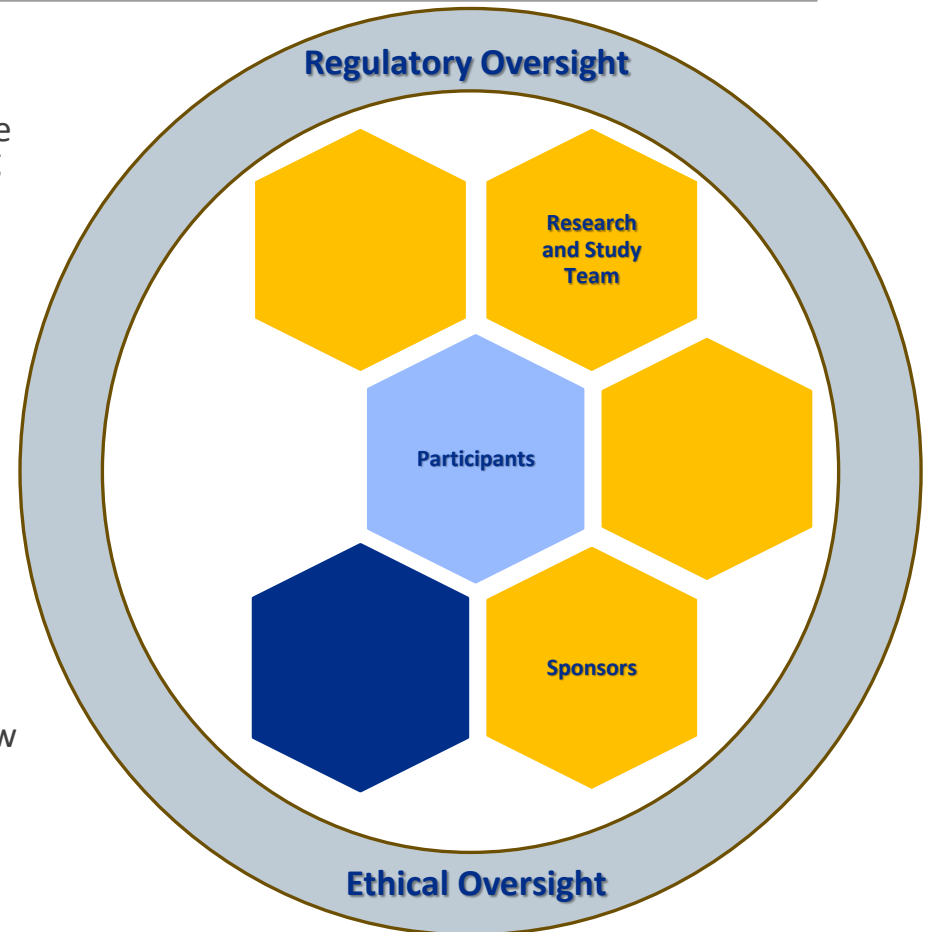
Investigators execute trials per protocols, manage recruitment, obtain consent, and ensure data quality ethically.

Sponsors and Oversight

Sponsors fund and oversee trial design, data analysis, and results reporting to ensure research integrity.

Regulatory and Ethical Oversight

IRBs and regulators protect participants and review safety and efficacy to uphold ethical standards.



Challenges in Recruitment, Retention, and Diversity

Recruitment Barriers

Enrollment challenges arise from lack of awareness, logistical burdens, mistrust, and restrictive eligibility criteria.

Retention Importance

Participant dropout reduces study power; clear communication and flexible scheduling improve retention.

Diversity and Inclusion

Underrepresentation limits findings and worsens health disparities; inclusive recruitment is essential.

Innovative Solutions

Community engagement and virtual trials help overcome recruitment and retention challenges effectively.

The Voice of The Patient

The Voice of the Patient: Living with Chronic Hepatitis B

Report of an
Externally-Led
Patient-focused
Drug Development
Meeting



HBV DRUG WATCH



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Treatment & Management

Medication Assistance
Programs in the U.S.

- Adults Living with Hep B
- Children Living with Hep B

Drug Watch

This detailed and up-to-date list is made possible by the hard work and research performed by the Hepatitis B Foundation. Please help us continue to offer this kind of essential resource for the treatment of hepatitis B with a donation toward our important programs. [Donate here.](#)

To learn more about the drug development process, [click here.](#)

Compounds in Development for Chronic Hepatitis B

<https://www.hepb.org/treatment-and-management/drug-watch/>



How to Find Clinical Trials



What Is
Hepatitis B?

Prevention &
Diagnosis

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Management

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Resources & Support

Cancer Prevention Media
Toolkit

Hep B Birth Dose Media Toolkit

Our Blog

Patient and Provider
Opportunities

Hepatitis B Foundation's
Discrimination Registry

+ Know Your Rights

Online Support Groups

Fact Sheets

+ Online Training

Glossary

B Informed Conference Videos
and Information

+ Patient-facing infographics

Patient and Provider Opportunities

The Hepatitis B Foundation is pleased to share information about current and upcoming opportunities for people living with hepatitis B and/or D and their providers. These opportunities can be tools and resources, clinical trials, or other research opportunities to learn more from people who have hepatitis B or coinfection with delta.

A clinical research study is now enrolling adults with chronic hepatitis B virus.



[Patient and Provider Opportunities » Hepatitis B Foundation](#)

How to Find Clinical Trials



What Is Hepatitis B?

Prevention & Diagnosis

Treatment & Management

Resources & Support

Research & Programs

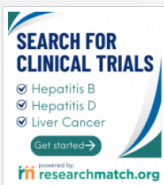
News & Events

Treatment & Management

Medication Assistance Programs in the U.S.

- Adults Living with Hep B
- Children Living with Hep B
- Pregnancy and Hep B
- Treatment Options
- **Clinical Trials**
- Locating Clinical Trials
- Physician Directory

Drug Watch



Clinical Trials for Hepatitis B

Welcome to the Hepatitis B Foundation's Clinical Trials Finder

The future is bright for people with chronic hepatitis B, thanks to recent advances in medical science.

NOTE: The Hepatitis B Foundation does not run or manage clinical trials but is sometimes asked to help promote certain drug clinical trials. Please [click here](#) to see current opportunities.

A potential drug only advances to a clinical trial, which means testing in humans, after the drug demonstrates safety and effectiveness in the pre-clinical phase. You can read more about the drug development process [here](#). And you can see a current list of drugs in development for hepatitis B on our Drug Watch page [here](#). You can also find drugs in development for hepatitis delta [here](#), and for liver cancer [here](#).



With so many clinical trials in the U.S. and worldwide, it can be hard to find the best one for you. The U.S. Library of Medicine manages www.clinicaltrials.gov, a large database that can help you find clinical trials around the world. Please note that clinicaltrials.gov does not review or approve studies listed on their site for accuracy, safety, or legitimacy of the listing.

To help you more easily find clinical trials that are specifically on hepatitis B, hepatitis D, or liver cancer drugs that may be right for you, the Hepatitis B Foundation has teamed up with Antidote to create a Clinical Trials Finder to help people find clinical trials. You can also refer to the "How to Search" resource on www.clinicaltrials.gov for additional help navigating the website.



[Clinical Trials for Hepatitis B » Hepatitis B Foundation](#)

Additional Helpful Resources

Treatment & Management

- Medication Assistance Programs in the U.S.
- Adults Living with Hep B
- Children Living with Hep B
- Pregnancy and Hep B
- Treatment Options
- **Clinical Trials**
- Locating Clinical Trials
- Physician Directory
- Drug Watch

Patients' Rights and Safety in Clinical Trials



Learn about Participants Rights in Clinical Trials

You must provide Informed Consent

- Before you decide to join any study, you will have to talk with either your doctor or the research team about the study. They will explain everything you need to know about the study, what you'll do as a participant, and any possible risks involved.
- After you understand what's involved in participating in the study, you'll be asked to sign an Informed Consent Form. This form confirms that you understand everything and agree to take part in the study before you officially join.
- Please be prepared; consent forms are long and contain a lot of information. It is best if you review the consent form with your healthcare provider, who can help you understand the information.

Your participation is Voluntary

- You have the right to choose whether to continue or leave the study at any time (withdraw consent). If you decide to stop, researchers will follow up with you.
- Participating in a clinical trial may require a commitment of your time, but you can always ask your research team for details about the specific time commitments involved.
- Although you can leave a clinical trial at any time, be sure to first talk to your doctor or nurse, let them know why you want to leave, and ask for their advice. It is important to have your doctor monitor your health if you decide to stop the clinical trial to make sure you are healthy.

Your Anonymity, Your Confidentiality



Treatment & Management

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How to Participate in a Clinical Trial

Requirements to participate in a clinical trial vary for each clinical trial, so it is important to review clinical trials near you to see if you qualify to participate. Not everyone who is interested in a trial will be accepted. In most cases, participants will need to be able to travel to a participating doctor on a regular basis for monitoring, although in some cases your regular doctor may be able to send in your regular results to the research team. Your doctor may be able to help you determine if there are clinical trials that may work for you. Always ask your doctor if they know about a clinical trial that may be right for you.



Remember, when you join a clinical trial, you will be working with the health care team that is associated with the trial – this might mean seeing a different doctor than you do now. Be sure to coordinate your care with your doctors.

Talking with Your Doctor About Clinical Trials

It is important to make an informed decision when considering a clinical trial, and talking to your doctor should be part of this process. Bring the information about any trials with you when you visit your doctor. Your doctor should be able to help explain the process of joining a clinical trial, so you can make a shared decision about what is best for you.

Your Doctor's Role in Clinical Trials

Talk to your doctor about clinical trials that may benefit you. Ask your doctor to help you sort through the pros and cons of enrolling in a clinical trial and the different treatment options.

Note: Even if your doctor doesn't know about any active clinical trials, you can still discuss any trials you find and ask for their advice or opinions. Don't stop your clinical trial search if your doctor says, 'I don't know.'

You are encouraged to see your health care provider regularly, even if you are in a clinical trial. Your doctor has been treating your condition and has expertise in what treatment plan is most appropriate for you.

Questions to Ask Your Doctor Before Enrolling in a Clinical Trial

1. Why should I participate in this study? How is this study going to help me?
2. How will my participation help others?
3. What are the potential risks of participating in clinical trials?
4. How would changing my medication or treatment plan affect my health?
5. If I am not scheduled to meet with the clinical trial team, can I come to you for help?
6. After the trial is over, or if I drop out of the trial, how can I return to my regular care?
7. Will you be receiving my test results during or after the trial?

You can learn more about helpful terms and definitions [here](#).



Our work!

Outreach

Understanding barriers and enablers to participate in hepatitis B clinical trials

Established the global hepatitis B & D Community Advisory Board (CAB)

Education

Hepatitis B Drug Watch

Questions to ask as you decide whether to participate in a clinical trial

Understanding your rights as a participants in a clinical trial

Partnership

Clinical Trial Finder (Research Match)

Collaborating with industry to promote their clinical trials

Policy and Advocacy

Advocating for more inclusive clinical trial design



HBF Public Health Research

- Document the lived experiences and quality of life associated with HBV, HDV, HCC
- Develop and test effective PRO instruments to include into clinical management and clinical trials
- Evaluate patient perspectives and preferences for current and future treatment
- Assess patient perspectives towards functional cure, partial cure, Long Acting Antiviral treatments
- Document socio-cultural beliefs related to HBV, HDV, HCC, and use evidence to build better education programs
- Assess attitudes and perceptions of PLWHB/D towards clinical trials
- Evaluate barriers and enablers to clinical trials and use evidence to improve access and patient centric-clinical trials



Storytelling

https://youtu.be/7EyfSuxYmbM?si=-0U1_3YO7gfYJPWp



Thank you

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www.hepb.org