HEPATITIS B® FOUNDATION

Understanding Clinical Trials

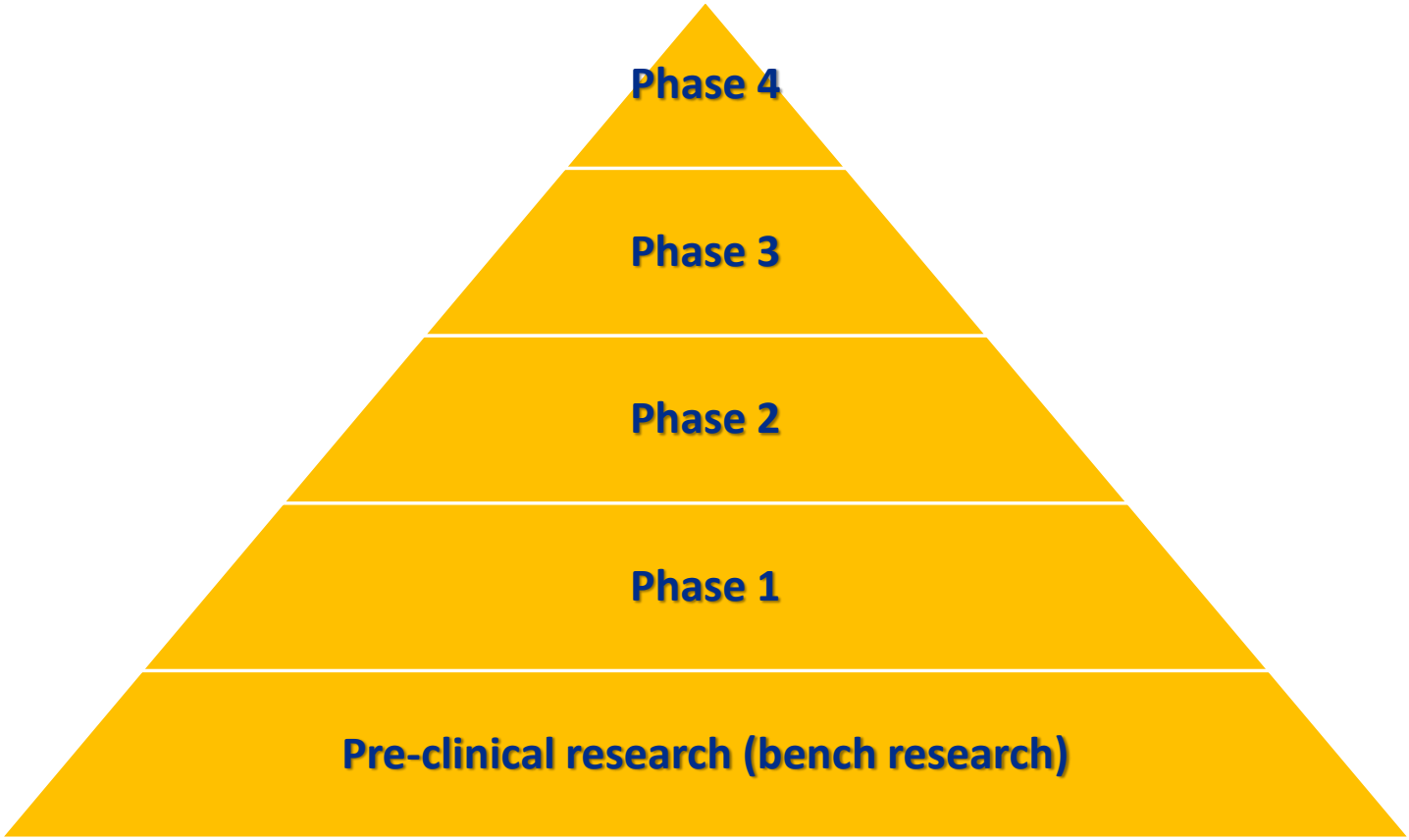
Yasmin Ibrahim MD, PhD

April 7th, 2026

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	- 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

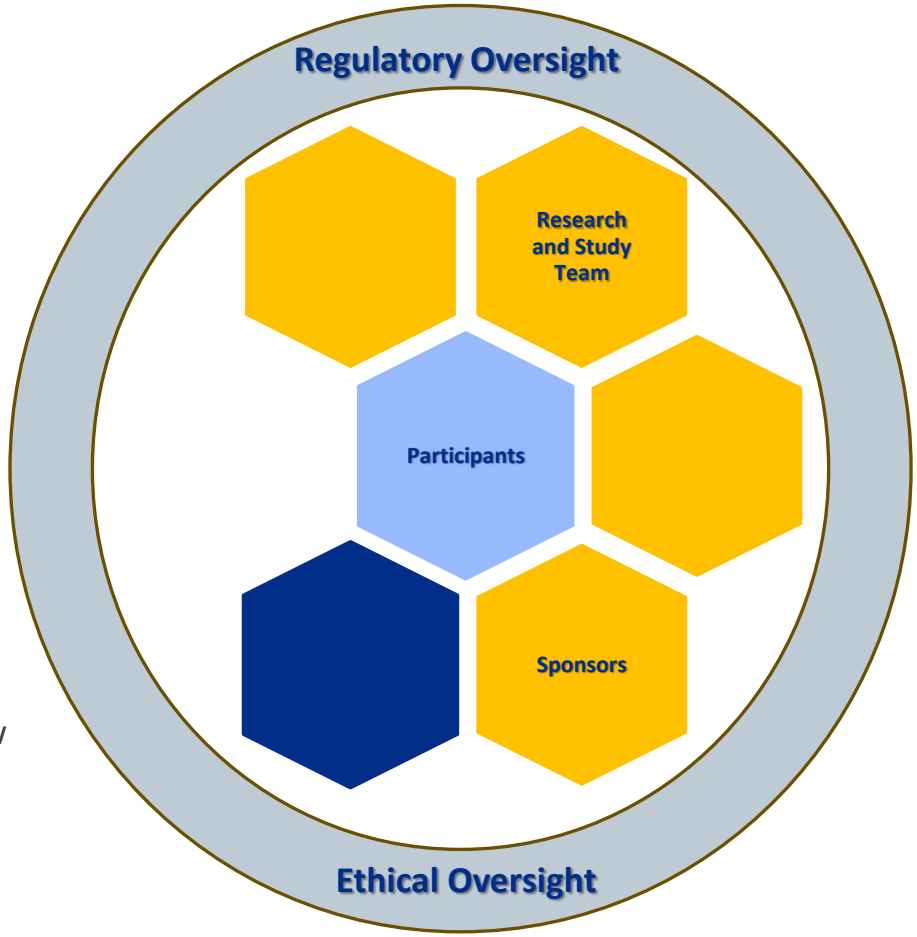
Investigators execute trials per protocols, manage recruitment, obtain consent, and ensure data quality ethically.

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.

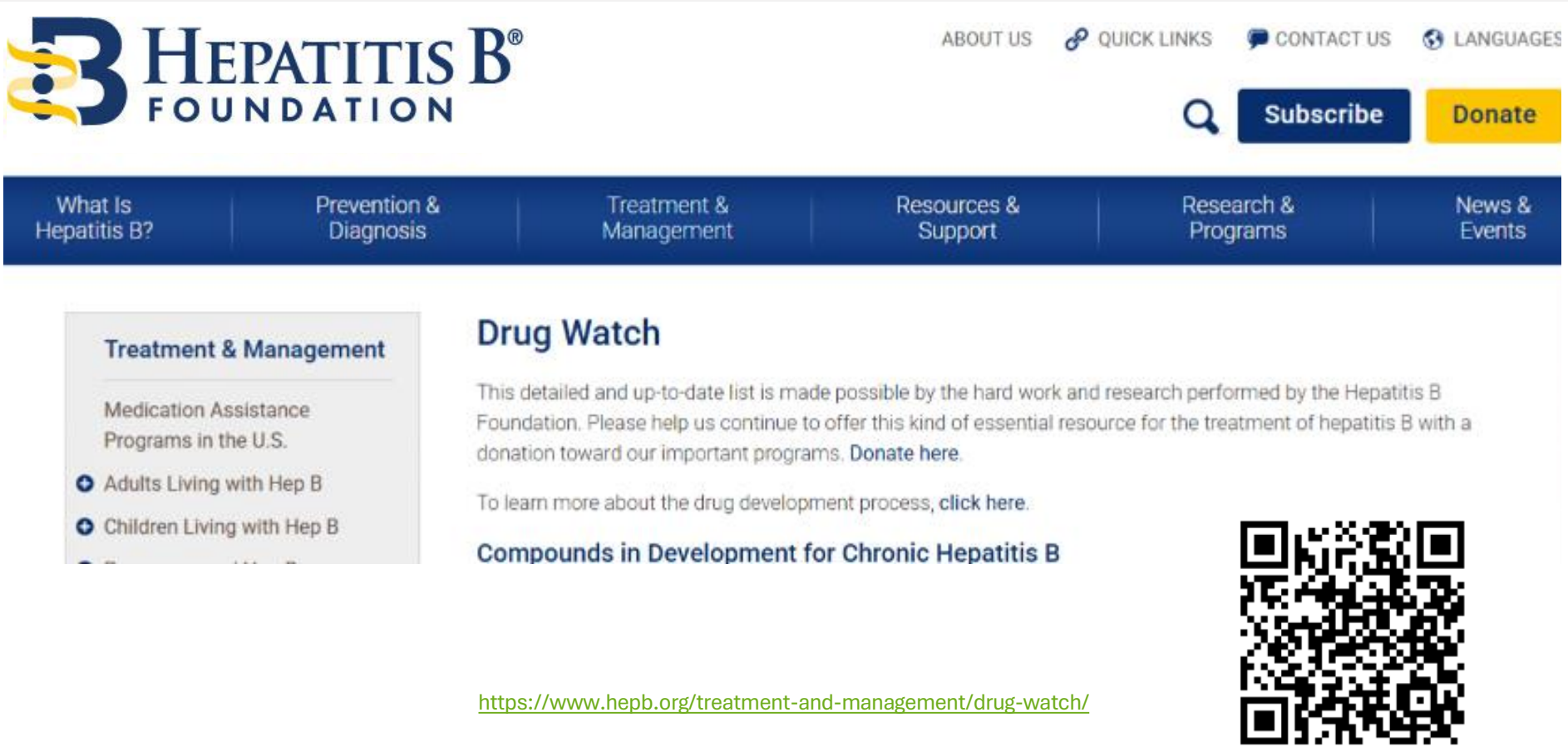
The Voice of The Patient

The Voice of the Patient:
Living with Chronic Hepatitis B

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

HEPATITIS B FOUNDATION
www.hepb.org

HBV DRUG WATCH



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

How to Find Clinical Trials

HEPATITIS B® FOUNDATION

What Is Hepatitis B? | Prevention & Diagnosis | Treatment & Management | Resources & Support | Research & Programs | News & Events

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

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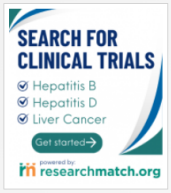
Treatment & Management

- 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

[Patients' Rights and Safety in Clinical Trials » Hepatitis B Foundation]

[How to Participate in a Clinical Trial » Hepatitis B Foundation]

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

yasmin.ibrahim@hepb.org

www.hepb.org