

GUIDANCE ON Clinical Trial Enrollment



You have PBC and your doctor has suggested a clinical trial might open the door for you to try a new medication in development to help slow down the progression of PBC and/or manage associated symptoms.

Here is what you can expect

To enroll in a PBC clinical trial, patients typically need to be at least 18 years old, have a confirmed diagnosis of PBC, meet specific criteria regarding liver function, and be willing to undergo regular monitoring and assessments while receiving a study medication.

Your doctor will help you contact a research center or clinical trials website to find eligible studies and discuss participation details with you.

Keep in mind these key points about PBC clinical trial enrollment

Eligibility criteria

Studies will have specific inclusion and exclusion criteria based on factors like age, PBC severity, current medications, medical history, and ability to comply with study procedures.

Screening process

Before enrollment, you will undergo a screening process including medical history review, physical examination, blood tests, and potentially liver imaging to confirm eligibility.

Informed consent

If eligible, you will need to sign an informed consent document thoroughly explaining the study details, potential risks and benefits, and their right to withdraw at any time.

Study procedures

Participation may involve regular visits to the study site for blood draws, assessments of symptoms like pruritus (itching), and possibly liver function tests.

Treatment arms

Clinical trials often include different treatment arms, which could involve receiving the study drug, a standard treatment like ursodeoxycholic acid (UDCA), or a placebo.



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How to find PBC clinical trials

ClinicalTrials.gov

The primary online database for clinical trials in the United States, searchable by condition (like “Primary Biliary Cholangitis”).

Patient advocacy organizations

Organizations like the PBCers Organization or the American Liver Foundation may list current PBC clinical trials and provide information for potential participants.

Healthcare provider

Consult with your doctor to discuss potential PBC clinical trials that might be suitable for your situation.

Important Things to Consider

- Before considering any clinical trial, thoroughly discuss the potential risks and benefits with your healthcare provider to make an informed decision.
- Some clinical trials may only be available at certain research centers, so consider the accessibility of the study site.
- Clinical trials can vary in length, so be aware of the commitment required for participation.

Clinical trials are critical to improving care for patients with PBC. Your interest in participating in a trial is a good thing not only for you, but for the entire PBC community! Thank you for your interest!

