

# A Long-Term Study of Elafibranor in Adult Participants With Primary Biliary Cholangitis

NCT06016842

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Status	RECRUITING
Phase	Phase 3
Sponsor	Ipsen
Enrollment	276 participants

## Key Eligibility Criteria

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### Inclusion (5)

- Male or female participants must be ≥18 years of age at the time of signing the informed consent.
- Participants with a definite or probable diagnosis of primary biliary cholangitis (PBC)
- Participants with cirrhosis at SV1. • Participants must be Child Pugh A or Child Pugh B.
- Contraceptive use by men or women should be consistent with local regulations regarding the methods of contraception for those participating in clinical studies.
- Capable of giving signed informed consent which includes compliance with the requirements and restrictions listed in the informed consent form (ICF) and in this protocol.

### Exclusion (38)

- History or presence of other concomitant liver disease including but not limited to:
  - i) Primary sclerosing cholangitis (PSC).
  - ii) Autoimmune hepatitis (AIH) by simplified Diagnostic Criteria of the International Autoimmune Hepatitis Group (IAIHG) e6, or if treated for an overlap of PBC with AIH, or if there is clinical suspicion and evidence of overlap AIH features, that cannot be explained alone by insufficient response to UDCA.
  - iii) Positive hepatitis B surface antigen (HBsAg). Participants with negative HBsAg and positive hepatitis B core antibody (HBcAb) may be eligible if hepatitis B virus deoxyribonucleic acid (HBV DNA) is negative.
  - iv) Hepatitis C virus (HCV) infection defined by positive anti-HCV antibody and positive HCV ribonucleic acid (RNA) (Note: Participants with positive anti-HCV antibody due to previously treated HCV infection, may be enrolled if a confirmatory HCV RNA is undetectable and sustained viral response has been documented).

... and 33 more (see full listing online)

## Locations (177 total)

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Arizona Liver Health, Tucson, Arizona, United States  
Arkansas Diagnostic Center, PA, Little Rock, Arkansas, United States  
Southern California Research Center, Coronado, California, United States  
... and 174 more locations