

# Liver Disease Clinical Development at Worldwide Clinical Trials



**30+**  
Countries



**5,000+**  
Patients



**4,000+**  
Network of Sites



Routinely partner with  
**500+**  
of the highest performing sites

Worldwide has a robust global operational team with 150+ combined years of experience in liver disease.

The team has an enhanced understanding of assessments and challenges unique to liver disease studies from Phase I to Phase IV related to:

- Protocol design
- Rapid site selection and start-up
- Recruitment and retention
- Clinical assessments
- Non-invasive diagnostic measurements
- Liver imaging modalities
- Biomarker composite scoring (NAFLD fibrosis score, FIB-4, APRI, FibroSURE™/FibroTest, ELF)
- Pathology (including liver biopsy collection, processing, and reads)

## Acute & Chronic Liver Disease Experience

- Non-Alcoholic Steatohepatitis (NASH)
- Non-Alcoholic Fatty Liver Disease (NAFLD)
- Alcoholic Hepatitis
- Autoimmune Hepatitis
- Cirrhosis
- Hepatic Impairment (Early Phase)
- Hepatocellular Carcinoma
- Primary Biliary Cholangitis (PBC)
- Primary Sclerosing Cholangitis (PSC)
- Acute-on-Chronic Liver Failure
- Risk Factors - obesity, insulin resistance, type 2 diabetes, hypertension, and dyslipidemia



“When addressing trial-related challenges, Worldwide’s approach is direct and reflects their deep experience, and we have complete confidence in their approach. They understand what it means to be a small market cap company and are cognizant of the budget, finding ways to manage spending more effectively.”

Dr. Todd Hobbs, CMO at Hepion Pharmaceuticals

The acute and chronic liver disease team understands the logistical and operational challenges of liver disease protocols and has established effective mitigation strategies to ensure successful high-quality delivery.



Enrichment of patient population to improve screening & enrollment



Advocacy outreach & support



Risk identification & mitigation



Patient voice

# Worldwide Liver Disease Experience



## Global and regional regulatory expertise for liver disease programs

- More than 20,000 submissions in 70 countries since 2020
- Planning and operationalizing chronic liver disease trials globally with the latest (in-country) regulatory intelligence
- Collaborative engagement with regulatory agencies
- Pre-submission meetings with the FDA and other regulatory agencies
- Utilizing expedited pathways and programs
- Assistance with biomarker qualification programs
- Guidance for critical path innovation meeting (CPIM)
- Pediatric strategic considerations (including preparation and submission of iPSPs and PIPs)



## Central laboratories with validated biomarkers and imaging partner



## Experience in liver biomarkers

- Metabolic
- Fibrotic
- Inflammatory/oxidative stress
- Omic markers
- Early indicators
- Imaging
- Liver biochemistry & function



## Expertise in liver imaging

- Whole organ volume analysis (liver and spleen volume)
- Hepatic fat fraction (MRI-PDFF)
- Liver stiffness (MR elastography)
- SAT/VAT fat depot segmentation
- Experience integrating vibration controlled transient elastography (VCTE) +/- controlled attenuation parameter (CAP) into NASH/NAFLD clinical trials



## Extensive CV outcome and adjudication experience

- Our experience executing outcome trials includes understanding the events, treatment, and outcomes
- These studies require event adjudication and working closely with Clinical Events Committees (CECs)

**Our scientific team has the expertise to support a preclinical compound strategy and the medical expertise to support protocol design and development.**

With our deep medical and scientific experience in liver diseases, Worldwide has you covered. For more information or to talk about your study, [contact us](#).



Worldwide Clinical Trials (Worldwide) is a leading full-service global contract research organization (CRO) that works in partnership with biotechnology and pharmaceutical companies to create customized solutions that advance new medications – from discovery to reality.

Anchored in our company's scientific heritage, we are therapeutically focused on cardiovascular, metabolic, neuroscience, oncology, and rare diseases. Our deep therapeutic knowledge enables us to develop flexible plans and quickly solve problems for our customers.

For more information on Worldwide, visit [www.worldwide.com](http://www.worldwide.com) or connect with us on [LinkedIn](#).