Worldwide Clinical Trials

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

- Metabolic dysfunction-associated steatohepatitis (MASH)
- Metabolic dysfunction-associated steatotic liver disease (MASLD)
- Autoimmune hepatitis
- Liver cirrhosis
- Hepatic impairment (early phase)
- Hepatocellular carcinoma
- Metabolic dysfunction and alcohol associated liver disease (MetALD)
- Primary biliary cholangitis (PBC)
- Primary sclerosing cholangitis (PSC)
- Acute-on-chronic liver failure (ACLF)
- 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's Liver Disease Experience

Global and regional regulatory expertise for liver disease programs

- 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

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)

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 MASH/MASLD clinical trials

Worldwide has you covered. Our scientific team has the expertise to support a preclinical compound strategy and the medical expertise to support protocol design and development. Contact us to learn more →

Worldwide
Clinical Trials

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.

For more information on Worldwide, visit www.worldwide.com or connect with us on LinkedIn.

Last Update: 20240430