



Liver research

Accelerate your liver clinical development with proven expertise

Clinical research capabilities across cholestatic, autoimmune and metabolic liver disease



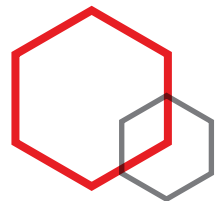
Advancing liver research: proven expertise for high-complexity delivery

Liver research is essential for improving the diagnosis, treatment and long-term management of chronic and rare liver diseases that affect millions of people worldwide.

Liver studies can face specific challenges, including identifying and enrolling appropriately staged patients, evolving standards of care, specialized assessments such as liver biopsy, non-invasive tests, imaging and histology and the burden of long-duration follow-up. Cholestatic, autoimmune and metabolic liver diseases are biologically heterogeneous and require careful selection of endpoints, biomarker strategies, disease-progression measures and treatment-response assessments. Many programs also require experienced sites and strong patient-engagement approaches to support retention and endpoint completion.

To maximize success, sponsors often turn to an experienced contract research organization with established liver expertise, site networks and an understanding of these complexities.

With 85 completed liver studies over the past five years, the PPD™ clinical research business of Thermo Fisher Scientific brings practical strategic and operational experience to programs where execution matters most.



Sponsors partner with Thermo Fisher Scientific for leadership in executing hepatology clinical trials:

Cholestatic liver disease expertise

- 16 completed PBC studies and two completed PSC studies in the past five years.
- Supported the successful delivery of studies contributing to the market approval of LIVDELZI® for PBC.
- Currently conducting PBC outcomes studies that generate longer-term data on safety, treatment response and disease progression to support regulatory requirements.
- Our team can enable sponsors to develop endpoint strategies that connect measures of disease activity, patient symptoms, patient-reported outcomes and long-term clinical outcomes.

MASH/MASLD trial-execution depth

- **31 completed MASH /MASLD studies** in the past five years, with an experienced operational team and deep medical experience.
- Liver-focused operational, medical and scientific expertise, including **nine in-house hepatologists/gastroenterologists** with MASH/MASLD experience.
- Clario, part of Thermo Fisher Scientific, brings advanced imaging capabilities and central reading to complement noninvasive testing and histology in MASH/MASLD studies.

Site networks built for liver-study delivery

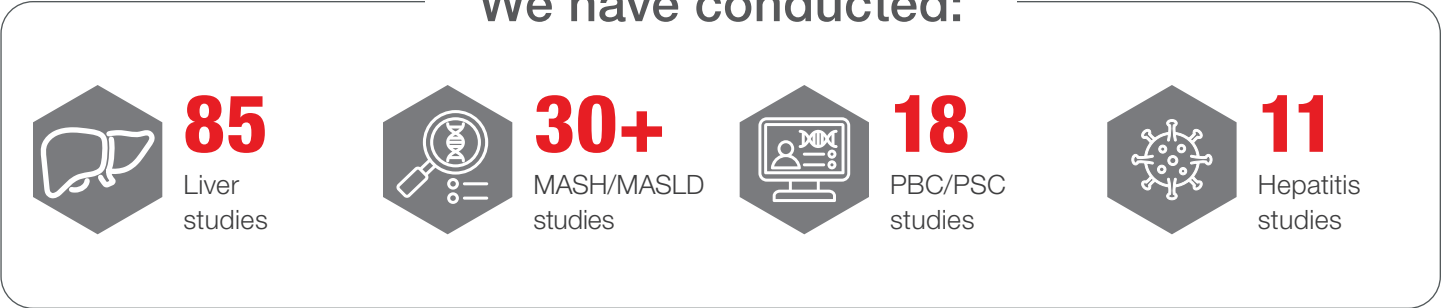
- **Site networks for complex hepatology trials:** Our experts match each protocol with sites that have the relevant patient access, specialist expertise and operational readiness. For MASH/MASLD, this includes access to appropriately staged populations and consistent delivery of biopsy, noninvasive testing and imaging. For PBC and PSC, it includes specialty hepatology expertise and access to rare cholestatic-disease populations.
- **Breadth across liver indications:** Our network supports programs in hepatitis, fatty liver disease, alpha-1 antitrypsin deficiency, glycogen storage disease type I, Wilson's disease, liver failure and other liver diseases.
- **Site intelligence at scale:** We map and analyze site capabilities in our databases, including disease-specific experience, patient access, biopsy readiness, non-invasive testing and imaging capacity, and protocol fit. With access to more than 6,000 hepatology and 7,900 GI sites, we can select sites aligned with each study's eligibility, geographic and evidence needs.
- **Close site partnerships:** PPD™ Select (PPDS) sites are established partners with a track record of high-quality data delivery, broad patient access and experienced principal investigators—supporting confident execution of complex liver studies.



Liver clinical research experience: focus where it matters most

Our experience spans rare cholestatic, autoimmune, metabolic, viral and inherited liver conditions. The study counts below reflect completed studies over the past five years.

We have conducted:

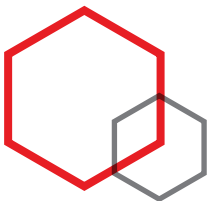


Our experience in key indications over the last five years encompasses:

Indication	Number of protocols	Number of sites	Number of patients
Alpha 1-Antitrypsin Deficiency	6	1,425	1,379
Glycogen Storage Disease Type I	16	72	163
Hepatitis	11	1,439	5,111
Liver Failure	1	1	79
MASH/MASLD	31	499	1,243
Primary Biliary Cholangitis	16	2,555	3,199
Primary Sclerosing Cholangitis	2	64	30
Wilson's Disease	2	29	95
Total	85	6,084	11,299

What our experience means for you

Our proven track record of executing complex hepatology clinical trials across PBC/PSC, MASH/MASLD and other liver indications helps sponsors build development plans around the challenges that matter to patients, sites and regulators.





Execution leadership for complex cholestatic disorders

PBC and PSC programs are defined by uncommon patient populations, evolving treatment options and the need to connect biochemical response, symptoms and long-term outcomes. Successful delivery requires a partner that understands the operational implications of all three.

We combine cholestatic liver-disease expertise with rare-disease recruitment, specialized site networks, endpoint-focused operations and patient-centered retention strategies to support high-quality PSC and PBC development programs.

A demonstrated contribution to PBC development

We supported the successful delivery of studies contributing to the market approval of LIVDELZI® for PBC.

Capabilities to support PBC and PSC studies

- Disease-specific expertise across PBC and PSC, combining hepatology, autoimmune cholestatic liver disease, IBD and biliary-disease knowledge.

- Specialized site networks across hepatology, gastroenterology, IBD and transplant centers, with access to MRCP-capable sites and well-characterized PSC and PBC populations.
- Targeted patient identification strategies, including identification of PSC patients through hepatology and IBD care pathways and PBC patients with inadequate UDCA response based on ALP, bilirubin and fibrosis-risk criteria.
- We combine specialty-hepatology study delivery with our in-house centralized imaging expertise, supporting protocol-defined imaging endpoints and biopsy/histology assessments where required by the study.
- Operational management of disease-specific complexity, including IBD and background therapy stability, cholangitis and antibiotic use, ERCP or stricture interventions, autoimmune overlap, symptom burden and cancer surveillance.
- Patient-centered recruitment and retention strategies addressing biopsy burden, travel, ePRO/eDiary completion, pruritus, fatigue, sleep disruption and adherence.

We are currently conducting PBC outcome studies to understand longer-term safety, treatment response, disease progression and clinical outcomes.

16

PBC completed studies

2

PSC completed studies

MASH/MASLD trials, made executable through integrated expertise, patient access and proven delivery

MASH/MASLD programs require far more than a traditional study operating model. Competition for appropriately staged patients, biopsy burden, non-invasive assessment strategies, co-morbidities and the need for durable evidence all raise the bar for trial delivery.

The PPD clinical research business of Thermo Fisher Scientific offers concrete data-driven and tested solutions for the successful clinical execution of your trial. We have significant experience conducting MASH/MASLD studies, which include patient-centric strategies and our very own imaging capabilities.

We work across hepatology and cardiometabolic care settings to build practical referral and pre-screening pathways for people with MASLD who may meet protocol-defined MASH and fibrosis criteria.

- **31+ MASH/MASLD** - Phase I-IV Studies in the past 5 years recruiting 1,200+ patients.
- **End-to-end biopsy management** - Biopsy operations with no blind spots. Full-service central laboratory support enables rapid biopsy logistics, preparation and automated tracking of biopsy results.
- **Liver-focused operational, medical and scientific expertise** including nine in-house hepatologist/gastroenterologist with MASH/MASLD experience.
- **Medical and regulatory insight that strengthens execution** - We bring deep understanding of MASH/MASLD medical and regulatory requirements, guiding study design around regulatory expectations for endpoints and evidence.
- **Our proprietary patient database** - 70K+ with self-reported fatty-liver disease including conditions associated with MASH and MASLD in our database.
- **Patient voice is built into MASH/MASLD study design** with our established Patient Advisory Board that brings real-world patient perspectives into protocol development, helping participant motivation and engagement.

Partner with us to benefit from our:

- Global MASH/MASLD depth of experience across Phase I-IV, with operational models for protocol complexity and long-term follow-up.
- Site networks selected for protocol-specific capability: fibrosis-stage population access, biopsy readiness, NIT/imaging capacity, activation and retention performance.
- Provision of educational materials for sites and a PI educational playbook alongside motivational interviewing to help recruit the RIGHT patient.
- Our study-delivery expertise is strengthened by in-house, non-invasive imaging capabilities that help sponsors create protocol-specific biomarker and imaging strategies. These include MRI-PDFF for liver-fat assessment and, where appropriate, MRE for liver stiffness. End-to-end imaging support, from charter development and site readiness through independent image review, quality oversight and rapid eligibility reads, reducing avoidable imaging-related screen failures and repeat scans, supporting timely enrollment and generating robust evidence of disease change.
- Our own home health services minimize patient burden while protecting endpoint integrity and high patient dropout rates.
- Recruitment and retention materials developed to address the specific challenges of MASH/MASLD studies, targeting not only the patient, but also the patient's surroundings (e.g., info sheets, counseling). Providing tools and incentives to keep patients motivated, especially in placebo-controlled trials, minimizing the dropout rate.
- Patient concierge services that provide appointment reminders, assist with transportation, medication reminders and enhance patient experience.
- Risk-based quality and data surveillance focused on critical-to-quality factors: eligibility and fibrosis staging, background therapies, lifestyle and weight changes, endpoint completion, premature discontinuation and site variability.
- Cardiovascular kidney metabolic (CKM) expertise that coordinates hepatology, endocrinology, diabetes, obesity, cardiology and renal perspectives across MASH/MASLD comorbidities.

Our proven track record



Improved site
engagement



On-time study
completion



Quick site
activations



Quality
data

One connected model for liver development

The PPD clinical research business of Thermo Fisher Scientific connects liver-specific clinical research with the capabilities to plan, manufacture and supply investigational product, execute studies, capture critical data and extend the evidence.

Supporting MASH/MASLD, PBC, PSC and broader liver-development programs



Liver strategy and protocol design

Therapeutic expertise, protocol and endpoint planning, regulatory affairs, medical writing and safety support.



Clinical manufacturing and IMP supply

Clinical manufacturing of investigational product, packaging and labeling, comparator sourcing, and global clinical supply logistics.



Specialty sites, patients and study delivery

Hepatology and GI site networks, feasibility, recruitment and retention, decentralized options, and global clinical operations.



Laboratory, endpoint data and imaging

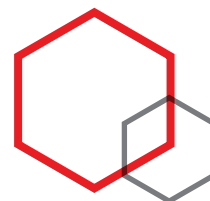
Central laboratory and biospecimen solutions, data management and quality, plus endpoint-data and medical-imaging capabilities from Clario, part of Thermo Fisher Scientific.



Long-term evidence and post-approval support

Longitudinal outcomes studies, pharmacovigilance, medical communications and evidence needs that extend beyond pivotal development.

Connected program management across development, supply, sites, data and evidence



Let's connect

Talk to the PPD clinical research business of Thermo Fisher Scientific about your liver development program.



Explore how our leadership in executing hepatology clinical trials can help advance your program with confidence.



Learn more at ppd.com/therapeutic-expertise/hepatology-cro/

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