

Clinical trials

We have the right MASH experience for a competitive environment

The competitive landscape for MASH and MASLD product development is rapidly growing with multiple studies already running or ready to begin. To maximize enrollment potential, it is important to get a study started as fast as possible. The PPD™ clinical research business of Thermo Fisher Scientific has an experienced team of MASH/MASLD medical and operational leaders to get your MASH study on the path to success quickly.



25 MASH/MASLD
studies ongoing or
completed



Over
400 sites
in 44 countries



>1,200
patients

Pathway to success – from start to finish

Given the current development landscape and the potential need for invasive biopsies, recruitment for MASH studies faces strong competition and potentially high screen failure rates. **We have the right partner to help you successfully navigate these challenges from early development through post-approval.**

- MASLD/MASH experience since 2010
- A deep understanding of the medical and regulatory requirements and the ability to provide consultation on all aspects of your study, including endpoints, protocol development and site strategy
- Rapid startup with known MASH sites and our dedicated sites with MASH experience
- Strong site relationships and experience with fast enrolling sites
- Refined patient pathway for an efficient diagnosis process including evaluation for the use of potential non-invasive assessments
- Retention planning through patient concierge services
- Sophisticated de-centralized trial solutions making challenging trials appeal to patients
- Handling of managing liver biopsies and processing with a full-service central labs support for rapid biopsy logistics, preparation, and automated tracking of biopsy results
- End-to-end solution, from manufacturing/packing/distribution of IP to early engagement/dose finding, through Phase II, III and peri-post approval service
- Diversity department to support with development of diversity action plan needed to meet FDA requirements
- Patient Advisory Board – to include Patient Voice in MASH protocol design
- **Our Cardiovascular-Kidney-Metabolic (CKM) Centre of Excellence** supports client with seamless cross-collaborative operational, medical and scientific expertise.

Leading site and patient access

>350 MASH
investigators
in our global
database



**Strong network of
sites** with MASH
experience with
experience in the
U.S. and Europe

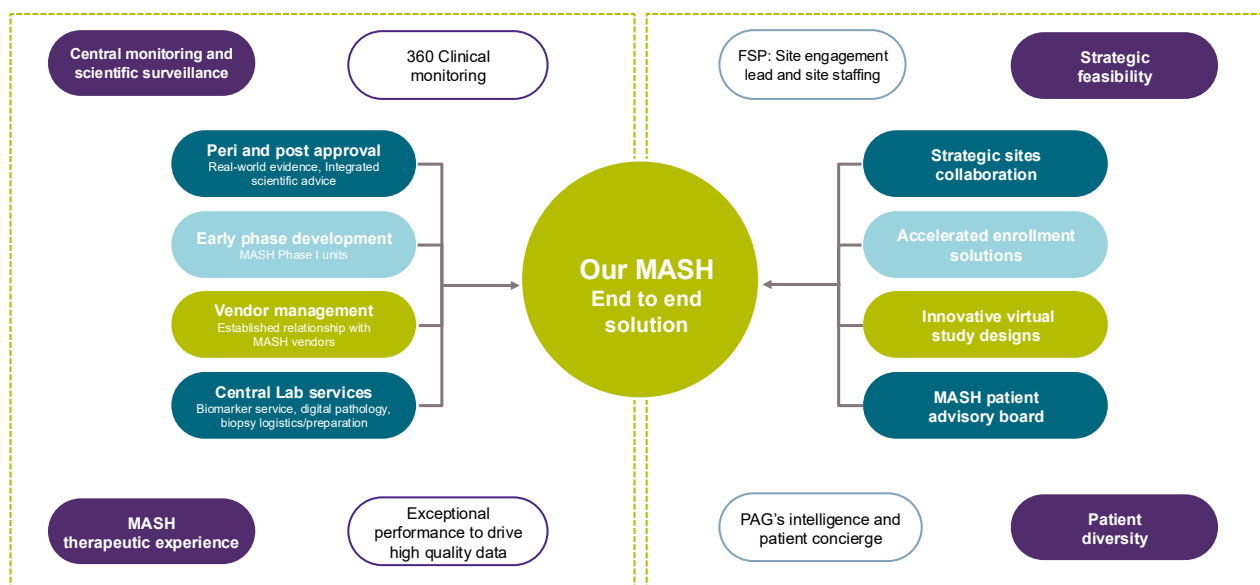
70K+ respondents
with self-reported
fatty-liver disease
including conditions
associated with
MASH and MASLD in
our databases



Our expertise and experience

MASH is a complicated disease that requires a broad range of expertise to operationalize. We can offer an end-to-end solution; from early development to commercialization. Our integrated MASH model offers a range of solutions and highly skilled professionals to meet all your study needs.

Our integrated MASH platform – end to end solution



Diversity and breadth of sources to drive successful study execution as an extension of your team

Our MASH experienced staff



240+ CRAs
globally with
MASH experience



30+
clinical team
managers



40+
project
managers



7
board-certified
gastroenterologists

The PPD clinical research business of Thermo Fisher Scientific is one of the leading CROs in MASH. Whether you are in early strategic planning or clinical development, we stand ready to partner with you to move your MASH treatments forward.

Learn more at thermofisher.com/ppd

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