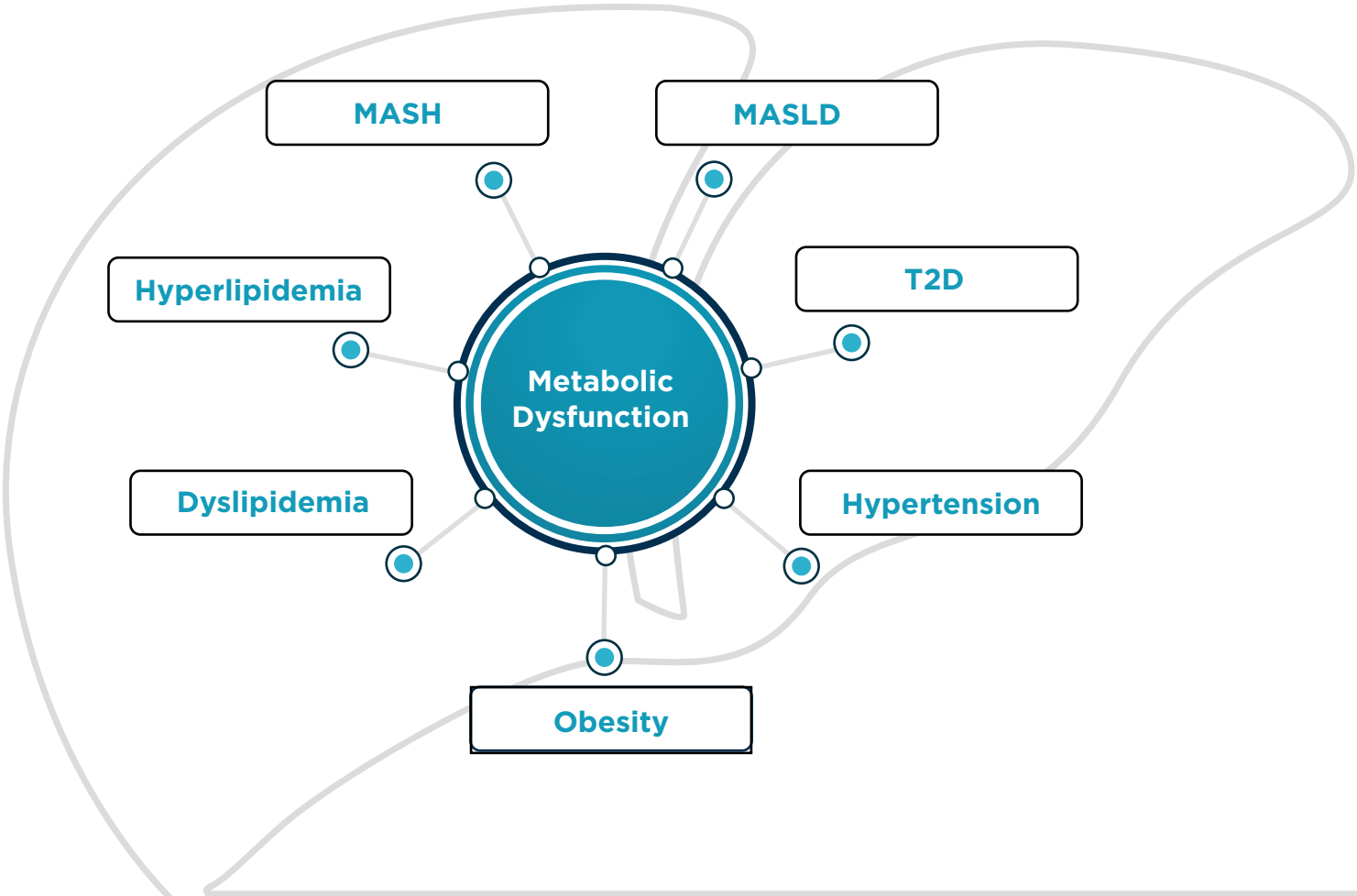
Worldwide Clinical Trials

MASH/MASLD Clinical Development at Worldwide Clinical Trials

We're committed to supporting your metabolic dysfunction-associated steatohepatitis (MASH) or metabolic dysfunction-associated steatotic liver disease (MASLD) trial with strategic clinical development services informed by the nature of these diseases. Leveraging our KOL and site relationships combined with our scientific expertise and personalized approach, we provide our sponsors with quality, data-driven solutions to drive trial success.

Our commitment to the clinical development of metabolic dysfunction therapeutics extends across all cardiovascular-kidney-metabolic diseases, from MASH and MASLD to type 2 diabetes, hypertension, obesity, dyslipidemia, and hyperlipidemia. We bring deep therapeutic, scientific, operational, and regulatory expertise to the development of treatments for these conditions, including advancing GLP-1 agonists.



Our MASH/MASLD Capabilities

Specialized Liver Imaging

- Whole organ volume analysis (liver, spleen and biliary system assessment)
- Hepatic fat fraction (MRI-PDFF)
- Liver stiffness (MR elastography)
- Fibro-inflammation (cT1)
- And more

Phase I Through Post-Marketing Approval Service

- Full-service support for Phase I-IV
- 200-bed in-house clinical pharmacology unit
- In-house bioanalytical lab into MASH/MASLD clinical trials

Enhanced Scientific & Medical Expertise

- Expertise in providing superior protocol design and development support
- Scientific solutions to support preclinical compound strategy

Global Operational Expertise

- Enhanced awareness of assessments and challenges unique to MASH/MASLD
- Clinical assessments:
  - Non-invasive diagnostic measurements
  - Biomarker composite scoring (MASLD fibrosis score, FIB-4, APRI, Fibrosure™/Fibrotest, ELF)
  - Pathology (including liver biopsy collection, processing, and reads)

Core Lab Partnerships

- Central labs and bioanalytical labs (PK/PD, biomarkers, and pathology)
  - Biomarkers in inflammation, fibrosis, steatosis, and metabolic
- Experience integrating vibration-controlled transient elastography (VCTE) +/- controlled attenuation parameter (CAP) into MASH/MASLD clinical trials

Key Global Industry Relationships

- Global network of top investigators and KOLs
- Access to 700+ global sites with experience in metabolic disorders – including 150 with MASH/MASLD expertise

Effective Recruitment & Retention Strategies

- Prioritization of the patient experience
- Relationships with patient advocacy organizations
- Strategic pre-screening and screening strategies to reduce screen failures and enrich recruitment
- Patient pathway mapping for enhanced patient outcomes
- Patient support services for burden reduction

Global & Regional Regulatory Support

- Local regulatory intelligence
- Regulatory agencies engagement
- Pre-submission meetings with the FDA
- Utilization of expedited pathways and programs
- Biomarker qualification programs
- Guidance for critical path innovation meeting (CPIM)

Meet Your MASH/MASLD Team

From their experience supporting MASH/MASLD clinical trials, our teams have amassed a wealth of expertise in dealing with expected and unexpected study challenges that arise in MASH/MASLD trials. Learn more about our team and what they can do for your study.

Michael Murphy, MD, PhD
Chief Medical and Scientific Officer

- 30+ years' experience
- Expert advice on protocol and study design
- In depth analysis and advice on operational feasibility of protocols
- Provides expertise in translational research services, strategic program development, and the facilitation of product commercialization

Sigrunn Blacoe, PhD
Executive Director, Project Management

- 20+ years of expertise in clinical trial planning and global program management across gastrointestinal, liver, and metabolic diseases
- Proven track record of leading complex multinational trials from feasibility through close-out, achieving accelerated timelines, optimizing global site networks, and implementing innovative strategies for recruitment, retention, and operational excellence

Sherilyn Adcock, RPh, PhD
Chief Scientific Officer, Early Phase Development

- More than 30 years of clinical research experience, primarily in Phase I/II drug development
- Responsibilities include evaluating the scientific, clinical, design, and logistical expertise for early clinical development projects.

Judith Hey-Hadavi, DDS, MD, MSc
Vice President, Medical Affairs

- 20+ years experience in global medical affairs, clinical innovation, and drug development (Phases 1–4) across diverse therapeutic areas including obesity, diabetes, MASH, and dyslipidemia.
- Distinguished academic and industry contributor with faculty appointments at Columbia, Rutgers, and Downstate Universities, 60+ publications, and recognition as one of the "25 Most Inspiring Women in Biopharma" (2024).

Alessandra Vignola
President, Cardiovascular & Metabolic

- 30+ years of experience in the pharmaceutical and clinical research industry
- Leads the Cardiovascular & Metabolic business unit at Worldwide, driving trial innovation and providing operational and strategic guidance for trial success

MarieElena Cordisco
Senior Director, Therapeutic Strategy Lead, Metabolic

- 17+ years of experience as a nurse practitioner with 10+ years of leadership in clinical research site management with a specialty in endocrinology
- Clinically active nurse practitioner and serves as principal and sub-investigator for cardiometabolic trials with publications in several peer-reviewed high-impact journals

To discuss your trial and see how our team and capabilities can support its success, contact us →