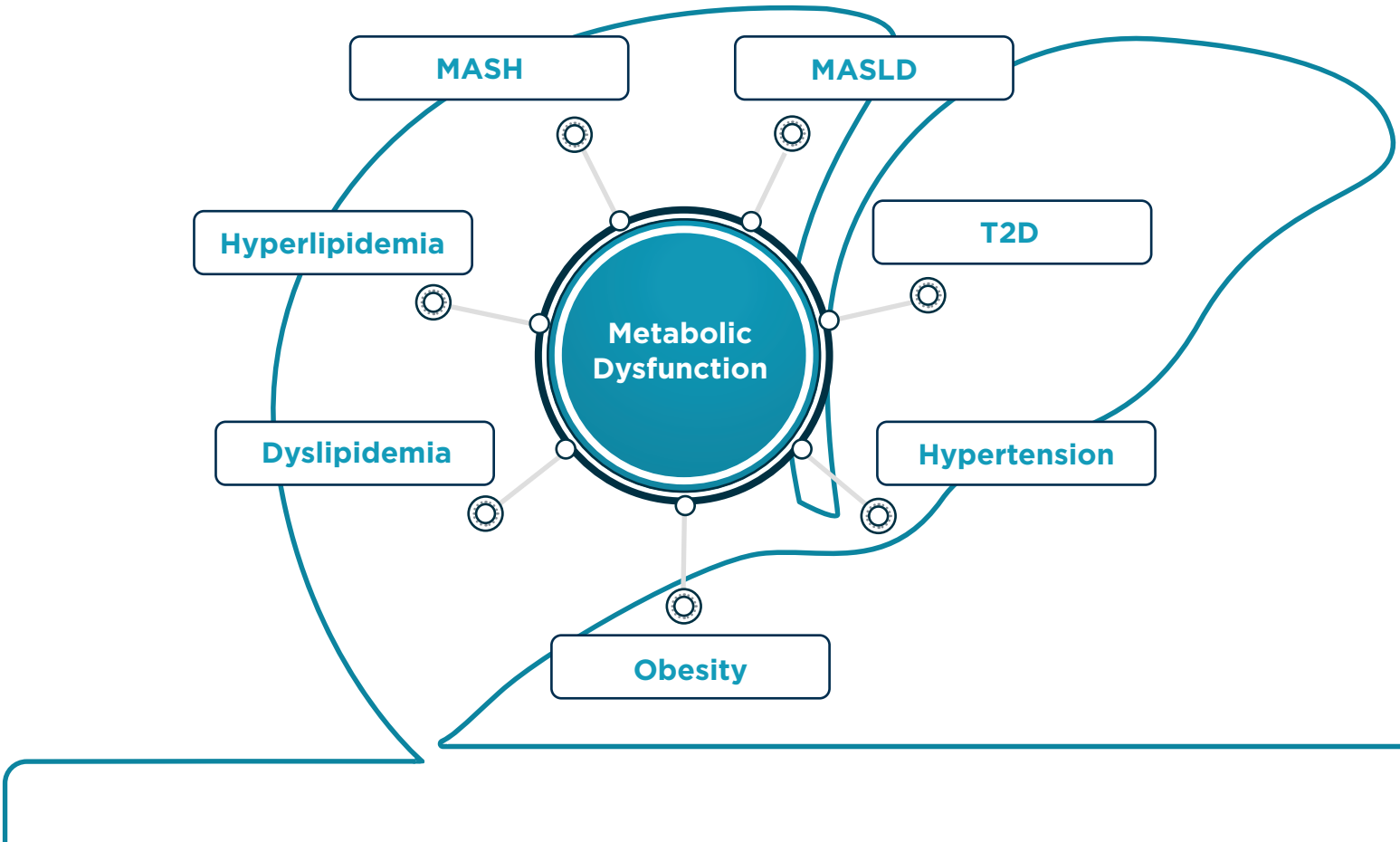
Worldwide Clinical Trials

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 have leading therapeutic, scientific, operational, and regulatory expertise for the development of therapeutics to address these diseases, including for the development of GLP-1 agonists for type 2 diabetes and obesity.



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

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

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

Key Global Industry Relationships

- Global network of top investigators and KOLs
- Access to 4,000 MASH/MASLD sites

Enhanced Scientific & Medical Expertise

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

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 Operational Expertise

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

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)

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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

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

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.

Attila Timar-Peregrin, MD, PhD, DVProf
Executive Director, Medical A ffairs, Metabolic, Gastrointestinal & Rare Disease

- 30+ years of experience of research experience as a preclinical and clinical researcher, study supervisor, principal investigator, chief investigator, and lead medical expert
- Has worked on 40+ clinical trials in gastroenterology, inflammatory and rare diseases, diabetic complications, and metabolic and hepatic conditions, including MASLD

Alexis Bailey, BSc, CCRA
Associate Director, Project Management

- Nearly 20 years in global and regional Phase I-IV clinical research
- Proven success in global leadership of MASH/MASLD trials across phases

Rafal Ziecina, MD, PhD, FFPM
Executive Director, Medical Affairs, Cardiometabolic & Inflammatory Diseases

- 20+ years of experience working in cardiometabolic studies
- Offers scientific and medical leadership of cardiovascular and metabolic research, including MASH/MASLD, and provides strategic services around filing, regulatory, and safety, and writing services for protocol and drug development plans

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