Why Celerion for NAFLD/NASH Development?

PROVEN EXPERIENCE:

With focused expertise and experience, Celerion is ready to assist you in accelerating your metabolic disease clinical development. Since 2007, Celerion has conducted over 100 studies for investigational products targeting metabolic diseases such as diabetes, obesity and nonalcoholic steatohepatitis (NASH). Our comprehensive NASH experience covers all aspects of drug development; from first-in-human to proof-of-mechanism studies to biomarker development. Our capabilities also expand to proof-of-concept and NDA labeling studies, such as drug-drug interaction and ADME studies.

INNOVATIVE ASSESSMENTS:

Imaging measure of steatosis and liver stiffness are important endpoints for early clinical phase studies. Celerion advances clinical trial execution through several state-of-the-art, noninvasive tools. FibroScan® technology is an ultrasound-like device that simultaneously measures liver fat and stiffness. FibroScan is available at our clinics in Lincoln, NE and Phoenix, AZ. Additionally, we have access to sophisticated imaging modalities such as magnetic resonance imaging proton density fat fraction (MRI-PDFF) for fat content determination and magnetic resonance elastography (MRE) for fibrosis assessments. Steatosis pathways can also be interrogated with stable-label isotope studies.

RELATED RESOURCES

- White Paper: Our Approach to NASH and Fibroscan
- Blog Post: Recommendations for NASH Drug Development
- Peer-Reviewed Article: Assay Validation and Clinical Performance of Chronic Inflammatory and Chemokine Biomarkers of NASH Fibrosis
- Research Article: Clinical Assessment of Hepatic De Novo Lipogenesis in Non-Alcoholic Fatty Liver Disease
- White Paper: Challenges and Solutions with Bioanalysis of Soluble Biomarkers: A Case Study for Non-Invasive NASH Biomarkers
- White Paper: Development and Validation of an ELISA for the CK18-M30 Apoptosis Biomarker for NASH Drug Development

ACCESS TO SUBJECTS:

As an experienced, full service CRO, Celerion offers a vast database of healthy volunteers for Phase I studies, as well as NAFLD subjects and access to biopsy-proven NASH patients. We have a robust database of >7000 obese but otherwise healthy participants and are rapidly building a NAFLD participant database using FibroScan. More than 350 subjects have already been pre-screened with FibroScan, including a full blood work-up. The approach reduces sponsor costs as it enables Celerion to pre-select eligible participants to undergo more costly imaging measures such as MRI-PDFF or MRE for inclusion criteria, reducing screen fails and expediting enrollment. Partnering with a network of patient sites, we have access to biopsy-proven NASH patients for a seamless transition to advance your drug program from first-in-human to proof-of-concept.

SOLUBLE BIOMARKERS:

Celerion's bioanalytical capabilities are able to support clinical studies with a breadth of technology. Platforms include ligand binding assays, cell-based functional assays, and molecular assays (e.g. qPCR). We have a library of analytically validated NASH biomarkers including CK-18, and apply a tiered approach to biomarker development.

NETWORK OF HEPATIC IMPAIRMENT CLINICS:

Since NASH drugs are intended for a hepatic impaired population, it is imperative to perform pharmacokinetic (PK) analysis to determine if dose adjustments are required. Celerion collaborates with expert centers specializing in hepatic and renal impaired PK studies. Our partner sites have a database of mild, moderate, and severe patients. Celerion provides full service management, streamlining the entire study saving you valuable time and costs. On average, we typically enroll a reduced study in 2 months, from first patient in (FPI) to last patient in (LPI).