prosciento®

ADVISE • ADVANCE • ACHIEVE

Nonalcoholic Steatohepatitis (NASH) *Drug Development Solutions*

ProSciento provides scientific and operational expertise in the design and management of all aspects of NASH clinical trials. Strengthened by deep therapeutic area knowledge and experience, ProSciento offers highly customized clinical R&D programs for clients globally, addressing the complexities of biomarker selection, access to eligible patients, and multinational clinical trial site access to specialized methodologies.

A Leading Provider of Clinical R&D Support for NASH Drug Development

9+

Years of experience in NAFLD & NASH

280+

Clinical projects completed in NASH, diabetes & obesity

NAFLD & NASH compound experience:

- FXR agonist
- miRNA-based therapeutics
- FGF21 analogs
- Cannabinoid 1 receptor modulators
- DGAT & ACC inhibitors
- Niacin derivatives
- Incretin-based therapeutics
- FGF & GPR receptor modulators
- and more...

Distinct Challenges in NASH Clinical Drug Development

The development pathway for NASH drugs is complex despite recent advances in the field. Distinct challenges for NASH clinical research include:

Few validated biomarkers and endpoints and uncertain regulatory pathways for drug approval

Crowded development space with **competition for clinical trial subjects and sites** for NASH clinical trials

Limited number of clinical trial sites with access to specialized methodologies and relevant NASH experience.

Science-Driven Strategies to Address Challenges in NASH Clinical Research

Targeted Biomarker Selection and Study Design

Strengthened by 15+ years in clinical R&D focused on metabolic diseases, ProSciento's scientific services team has deep expertise in selecting and deploying proven biomarkers and complementary advanced methodologies for NASH clinical research. We assist clients in designing studies utilizing biomarker insights for specific metabolic pathways, including, but not limited to, glucose homeostasis, lipid metabolism, inflammation, fibrosis and liver dysfunction. The services and expertise ProSciento provides to clients are further bolstered by scientific partnerships, including a NASH advisory board bringing together renowned scientists from leading academic institutions, and technology partnerships, including innovators in advanced imaging and circulating biomarkers.

Patient Access and Enrichment Strategies

ProSciento provides unique, effective solutions to considerably improve patient access and enrichment in the enrollment phase of NASH clinical trials. One such solution is ProSciento's patient pre-screening methodology to identify patients with steatosis or steatohepatitis prior to imaging techniques or biopsies. The noninvasive methodology utilizes vibration controlled transient elastography (VCTE) FibroScan, proprietary clinical algorithms, and state-of-the-art metabolomic testing. The outcome is a wider number of eligible patients and detailed enrichment data for the enrollment phase of a NASH clinical trial, and far fewer screen failures during expensive imaging procedures.

Science-Driven Clinical Trial Design and Management

A significant challenge in NASH clinical research is the limited number of sites with access to complex methods and tools, including MRI-PDFF, MRE and biopsy capabilities. ProSciento's hub & spokes clinical trial management platform solves this challenge by directly establishing and managing site access to specialized methods. What is unique to ProSciento's platform is the integration of its specialized method hubs and global network of clinical trial sites with operational and scientific acuity established from nearly a decade of experience in NASH and 15 years as a clinical research center of excellence for metabolic diseases.

Key Components Include:

HUBS – Centers with Specialized Methodologies

ProSciento has a global network of **45+ method hubs**, which are specialized centers with capabilities in liver biopsies and advanced imaging, including MRI-PDFF, MRE and VCTE FibroScan.

SPOKES – Qualified Clinical Trial Sites Near Each Hub

ProSciento manages the relationship between its global network of **200+ clinical trial sites** and its network of specialized method hubs. To ensure efficiencies for complex multi-site NASH studies, clinical trial sites are selected within geographic proximity of pre-qualified method hubs. This removes the burden from individual sites to procure access to specialized methods. This also broadens the number of sites that can participate in a study and increases access to patients to participate in clinical trials.

ProSciento's Approach for Highly Effective NASH Clinical Research Programs

Science-driven selection and utilization of biomarkers and methods

Focused pre-screening and patient enrichment strategies

Multi-site trial management, including site access to specialized methods

Full-scope CRO services, leveraging 15+ years of metabolic experience

Contact us at bd@prosciento.com to discuss your NASH drug development program

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