proSciento®

ADVISE • ADVANCE • ACHIEVE

Nonalcoholic Steatohepatitis (NASH) *Drug Development Solutions*

ProSciento provides scientific and operational expertise in the design and management of all facets of clinical development for NASH studies. Strengthened by focused therapeutic experience, ProSciento conducts highly customized clinical R&D programs for a global client base, addressing the complexities of biomarker selection, patient access, clinical trial design, and site access to specialized methodologies.

Premier Provider of Clinical R&D Support for NASH Drug Development

12+
Years of experience in NAFLD & NASH

350+
Clinical projects completed in NASH, diabetes & obesity

NAFLD & NASH compound experience:

- FXR agonists
- Incretin therapeutics, e.g. mono, dual & triple receptor agonists
- FGF-1, 19, 21 analogs
- Cannabinoid 1 receptor modulators
- DGAT & ACC inhibitors
- GPR modulators
- miRNA-based therapeutics
- 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, further complicated by uncertain regulatory pathways for drug approval

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

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

Science-Driven Strategies to Address Challenges in NASH Clinical Research

Targeted Biomarker Selection and Study Design

Strengthened by nearly two decades in clinical R&D focused on metabolic diseases, ProSciento's scientific services team has unparalleled expertise deploying biomarkers and 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 innovators in imaging and circulating biomarkers. ProSciento is also founder of the NASH Roundtable, a forum of renowned hepatologists, endocrinologists and clinical development experts to advise biopharma and advance NASH therapeutic development.

NASH PASS®

Patient Access and Screening Strategies

ProSciento's NASH PASS® is a science-driven clinical development platform, leveraging more than a decade of NASH therapeutic and operational expertise, and overcoming enrollment challenges inherent in NASH clinical trials. The platform streamlines and substantially improves site selection, patient access and enrollment for NASH clinical trials. It is also an important, evolving tool to enhance scientific knowledge of NAFLD and NASH disease progression, as well as to gain insight into the utility of diagnostic and prognostic biomarkers for clinical research. NASH PASS integrates three science-driven elements: a proprietary screening methodology utilizing predictive algorithms and a broad range of assessments; an IRB-approved clinical protocol deployed at strategic sites across the US; and a searchable NASH registry of current diagnostic data for research-ready patients.

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 acumen established from nearly a decade of experience in NASH and two decades as a clinical research center of excellence for metabolic diseases.

Key Components Include:

HUBS – Centers with Specialized Methodologies
ProSciento has a global network of **55+ 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 **250+ 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.

NASH hub & spokes™

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

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