

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*

10+

Years of experience
in NAFLD & NASH

280+

Clinical projects completed
in NASH, diabetes & obesity



NAFLD & NASH compound experience:

FXR agonists

miRNA-based therapeutics

FGF-1, 19, 21 analogs

Cannabinoid 1
receptor modulators

DGAT & ACC inhibitors

GPR modulators

Incretin therapeutics, e.g. mono,
dual & triple receptor agonists
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 15+ years 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 provides unique, science-driven solutions to considerably improve patient access and enrichment in the enrollment phase of NASH clinical trials. ProSciento's clinical trial sites utilize the NASH PASS protocol to identify patients with a high probability of 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, 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 acumen 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



Study
Design &
Biomarker
Utilization

Biomarker selection and
clinical trial design expertise

NASH
PASS™

Patient access and screening
strategies to significantly
improve enrollment rates

NASH
hub &
spokes

Multinational trial
management and site access
to specialized methods

Study
Conduct
& Data
Analysis

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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