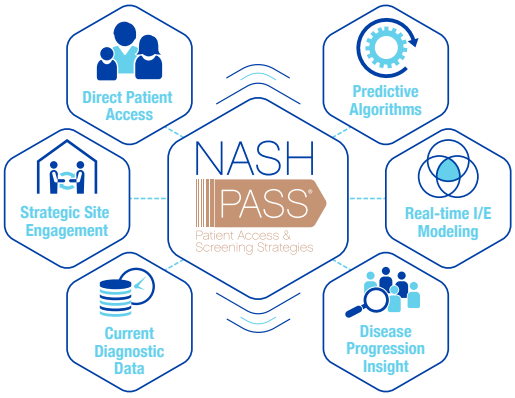
NASH PASS®

Patient Access & Screening Strategies

Improving Patient Enrollment and Streamlining Site Selection for NAFLD and NASH Clinical Trials

ProSciento's NASH PASS® is a science-driven clinical research and patient registry platform, leveraging more than a decade of NASH therapeutic and operational expertise, and designed to overcome 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 the scientific knowledge of NAFLD and NASH disease progression and the development of novel biomarkers for clinical research.



What is NASH PASS:

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.

Clinical Research Methodology

Developed and led by a scientific team with unparalleled experience and expertise in NASH clinical research

- Contributing to the understanding of disease progression and biomarker development and validation

Clinical Study Protocol

IRB-approved protocol to prescreen patients at prequalified sites from our network

- Proprietary predictive algorithms + clinical assessments + FibroScan
- Assessing patients at-risk for NASH
- Investigates associations between clinical assessments and biomarkers

Patient Registry

Searchable patient data utilized for clinical trial enrollment and analysis of disease progression

- Real-time and longitudinal data to optimize I/E criteria
- Data includes medical history, circulating and imaging biomarkers, and biopsies

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The NASH PASS Methodology and Clinical Protocol:

The methodology at the foundation of the NASH PASS program was developed and fine-tuned over the last decade within ProSciento's specialized clinical research unit in California. It is now exported in a highly controlled manner at strategic clinical trial sites across the U.S. The NASH PASS methodology utilizes clinical assessments, vibration controlled transient elastography (VCTE) FibroScan imaging, proprietary predictive algorithms, and data compilation and analysis. The IRB-approved clinical protocol employing this methodology is managed by ProSciento's team of experts and conducted at prequalified clinical provider locations, providing patients an opportunity to participate in clinical research through their existing healthcare providers.

The NASH PASS Patient Registry and its Impact on Clinical Trial Enrollment and NASH Science:

NASH PASS is a powerful platform to improve enrollment and site selection for NAFLD and NASH clinical trials. The NASH PASS patient registry compiles real-time and longitudinal data for prescreened patients ready for enrollment and prequalified sites ready for an expedited study launch. For study sponsors, the benefits include optimized I/E criteria utilizing a sample data set; streamlined site selection; study start within three months; and front-loaded enrollment for the first three months to significantly improve overall study timelines.

Because of the nature of the data, the NASH PASS registry is also an important instrument to enhance scientific knowledge of NAFLD and NASH disease progression and the utility of diagnostic and prognostic biomarkers.

NASH PASS Impact on Timelines, Cost and Enrollment:

	Industry	vs. NASH PASS® Patient Access & Screening Strategies
Regulatory	**Typically 6 MONTHS** Often site selection is extended to outside the US for added patient access, increasing cost and time	**1 MONTH** utilizing NASH PASS-engaged sites in the US, thereby reducing associated regulatory costs
Study Start	Site selection alone is generally **4 MONTHS**	Sites selected and prequalified in the NASH PASS registry available for immediate start All sites screening in **< 3 MONTHS**
Enrollment	**DELAYS** due to enrollment difficulties and resulting protocol amendments, often to adjust I/E criteria	Front-load enrollment to significantly improve study timelines **100% ENROLLMENT** on time when utilizing NASH PASS for I/E parameters

Premier Provider of Clinical R&D Services for NASH, Diabetes and Obesity

12+ Years of experience in NAFLD & NASH

350+ Clinical projects completed in NASH, diabetes & obesity

220+ Clinical trial sites

30+ NASH PASS - engaged sites

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