



NASH Council

Corporate Membership

Letter of Invitation

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Background

It is estimated that at least 25% of the global population has nonalcoholic fatty liver disease (NAFLD), defined as a liver with 5% or more fat. Of this population, 1 in 4 is estimated to have nonalcoholic steatohepatitis (NASH), characterized by increasing amounts of cell damage including fibrosis and liver inflammation. Untreated, these conditions can lead to cirrhosis, liver cancer, and the need for liver transplantation. NAFLD and NASH may develop into a life-threatening state without noticeable symptoms.

Although NASH was discovered almost 40 years ago, many challenges remain to understand its natural history and to optimize diagnosis and management. For example:

- NASH is a chronic yet sometimes asymptomatic disease, which means that most people live with the disease for several years with only diffuse symptoms.
- NASH can progress to severe health complications, including end-stage liver disease, liver cancer, primarily hepatocellular carcinoma (HCC), and death.
- People with NASH are at high risk of developing diabetes, metabolic syndrome, chronic kidney disease, and cardiovascular disease (CVD).
- Cardiovascular disease is the leading cause of death among people with

NASH.

- There is currently no consensus for a single non-invasive test to diagnose NASH and replace liver biopsy, a risky, invasive, and expensive procedure that is subject to sampling variability and should be a diagnostic test of last resort. However, there are active attempts to develop and validate tests to reduce the risks and costs of biopsy.
- There is still no approved pharmaceutical treatment available for NASH. Liver transplantation is the only recourse for people with end-stage liver disease and/or NASH-related HCC.



- NASH-related HCC is emerging as the fastest-growing cause of liver transplantation in the United States.
- Awareness of liver health, and NASH, in particular, is poor among the general public and clinical professionals.

These circumstances beg for well-coordinated public health, liver, and NASH-specific policy and advocacy collaboration, which GLI has created with the NASH Council.

NASH Council Membership as a Solution

Global Liver Institute's NASH Council is a multi-stakeholder collaborative designed to bring NASH and NAFLD to the forefront of public health concerns and priorities. GLI aims to ensure that the public and every patient worldwide has access to the entire spectrum of preventatives, diagnostics, and therapeutics afforded by modern medical science to prevent liver disease and its progression. For GLI, this is an urgent mission that encompasses our efforts addressing health policy, patient advocacy, public awareness, and related disorders like liver cancer.

The NASH Council provides and ensures a deep focus on the critical issues for NAFLD and NASH patients. Since its launch in 2017, over 80 organizations have joined the Council representing disparate sectors including patient advocacy organizations, ethnic health organizations, medical societies, government agencies, and corporate members. GLI's engagement, reach, and impact have grown.

NASH has become a part of healthcare policy discussions. We have raised and are bringing patient voices and concerns to the table. We note our victories, but not surprisingly, we have reached a new phase of engagement when resistance to patient-centric policies and established practices must be overcome. These challenges are one way we clearly know we are engaged and GLI has the confidence to know that with our expanding team and partner support we will prevail in fighting for patient interests.

GLI has been the singular patient organization representing liver patient needs and perspectives with the Institute for Clinical and Economic Review, the Food and Drug Administration (FDA), insurers, and others, including establishing helpful practice standards that include use of emerging diagnostic and treatment technologies. The next 12-24 months are critical to achieving new NASH-related medical realities for patients.

Council Goals

Policy

Advance a patient-led, NASH-specific agenda in the U.S., and abroad via legislation, policy and program initiatives, and within public health agencies to increase their NASH focus and activities.

Clinical Workflow

Optimal Patient Pathways - Through the NASH Council and with partner organizations and professional societies, promote the development of guidelines for standards of care and care pathways.



Clinical Trials - Grow wrap-around support services for NAFLD/NASH patients considering and in clinical trials through partnering to facilitate patient-centric clinical trial design and protocol review, patient education of clinical trial-specific issues, developing patient community engagement, and the creation and distribution of educational materials. *Medical Training* - Work with partner organizations and medical specialty organizations to implant NASH in medical training, including all specialties and allied professions engaged in NASH care.

Lifestyle

Nutrition/Physical Activity - Continue to build support of nutrition and physical activity planning, services, and education through the distribution and promotion of GLI nutrition app, advancing partnerships for food and exercise as medicine, education on tailored physical activity/nutrition options for liver patients, and policy support (e.g., coding/reimbursement, medical nutrition, etc).

Communication

Awareness/Education - Build on the *U.S. NASH Action Plan* to create action plans in other countries, leverage the opportunities afforded by International NASH Day, and use publicity and social media to continue to raise awareness about NAFLD/NASH and the risk posed by related conditions, particularly diabetes.

Beyond the Biopsy: Non-Invasive Diagnostics Campaign

Continue aggressive measures to promote non-invasive diagnostics and to achieve insurance reimbursement. The Beyond the Biopsy Campaign also creates awareness of best practices for screening and diagnostic options for NAFLD/NASH patients and presents independent support opportunities for upcoming roundtables, publication of best practices, and multilingual education and events.

Achievements

Since the creation of the NASH Council, GLI has:

- Introduced The NASH Care Act of 2020 in the U.S. Congress "to establish a Federal strategy for preventing, diagnosing, and treating nonalcoholic steatohepatitis." GLI has worked closely with U.S. Rep. Dan Crenshaw who introduced the legislation.
- Created the first U.S. NASH Action Plan, a short- and long-term national program of initiatives designed to overcome key NASH issues including insufficient awareness and education, lack of progress or consensus on use of non-invasive diagnostics, need for updated patient management standards, and efforts to achieve health system preparedness for NASH patients.
- Developed and issued the NASH Council report, *The Language of NASH: A Narrative Guide to Communication on NASH* to provide a foundational messaging framework for communication about NASH and NAFLD;
- Developed a focused campaign on non-invasive diagnostics called *Beyond the Biopsy*;
- Launched a personalized nutrition app in partnership with Nutristyle Inc. for people living with liver disease, diabetes, and other chronic conditions or who want to maintain good liver health. The app



creates personalized meal plans to meet the specific requirements set out by GLI nutritional advisors for people with NASH or a general interest in liver health;

- Achieved approval for ICD-10 coding changes at CMS/CDC to improve the ability to distinguish early and advanced hepatic fibrosis along with a note for these to be coded with NASH in the medical record, benefiting patients, physicians, epidemiologists, economic, and health system researchers;
- Launched an online CME resource in collaboration with NASH Council member, Clinical Care Options, to improve health care provider understanding of foundational concepts in NASH diagnosis, management, and emerging pharmacologic treatment strategies - including advanced practice clinicians, in hepatology, gastroenterology, endocrinology, and primary care. The full curriculum includes CME/CE-certified modules, ClinicalThought™ expert commentaries, and downloadable presentations and resources;
- Promoted NASH disease awareness with Summit Clinical Health at COVID-19 vaccination sites in the U.S. Southwest via partnerships with city vaccine centers and direct patient education;
- Led consecutive International NASH Day events featuring more than 120 partners from over 70 countries;
- Became regular panelists and contributors to the weekly *Surfing the NASH Tsunami* podcast where drug developers, investors, researchers, and corporate executives discuss what is happening in the commercial development of NASH medications.

Investment

Your company's involvement in the **NASH Council** will contribute to shaping policies, advancing clinical practices, promoting lifestyle support, and raising awareness about pediatric and rare liver diseases globally.

GLI invites your company to become a corporate member of the NASH Council, offering the following benefits:

- Two representatives on the Council
- Opportunity to suggest Council members and agenda topics
- Participation in in-person and virtual Council meetings and workgroup calls
- Access to GLI Council member portal and directory
- Unlimited subscriptions to GLI News updates
- Acknowledgment as a NASH Council Corporate Member
- Opportunity for signature sponsorship of Council initiatives

Cost: \$50,000



Your company's involvement in the NASH Council will contribute to shaping policies, advancing clinical practices, promoting lifestyle support, and raising awareness about NAFLD and NASH globally. By supporting the NASH Council, you align with a dedicated community working towards patient-centric standards of care, ultimately improving liver health outcomes for individuals worldwide.

About Global Liver Institute

Global Liver Institute (GLI) is a 501(c)3 nonprofit organization founded in the belief that liver health must take its place on the global public health agenda commensurate with the prevalence and impact of liver illness. GLI promotes innovation, encourages collaboration, and supports the scaling of optimal approaches to help eradicate liver diseases. Operating globally, GLI is committed to solving the problems that matter to liver patients and equipping advocates to improve the lives of individuals and families impacted by liver disease. GLI holds Platinum Transparency with Candid/GuideStar, is a member of the National Health Council, and serves as a Healthy People 2030 Champion. Follow GLI on Facebook, Instagram, LinkedIn, and YouTube or visit www.globalliver.org. GLI is the global host of Global Fatty Liver Day.

