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Gilead Sciences, Inc.

Medical Affairs

Request for Proposals (RFP) for NASH Models of Care Program

Non-alcoholic fatty liver disease (NAFLD) represents a spectrum of disease that ranges from simple fatty liver (steatosis; NAFL) to fatty liver with cell inflammation and ballooning (non-alcoholic steatohepatitis; NASH), which can progress to liver fibrosis and ultimately cirrhosis, liver failure, hepatocellular carcinoma (HCC) and death. NASH, particularly advanced fibrosis due to NASH, represents a significant unmet medical need, for which there are no approved therapies, limited noninvasive screening, diagnostic and monitoring tools, and poorly defined models of patient care.

Patients with advanced fibrosis due to NASH commonly have comorbid metabolic conditions, including obesity, type 2 diabetes mellitus (T2D), and dyslipidemia. Many of these conditions are key predictors for the development and progression of fibrosis due to NASH. Among the most common risk factors for NASH, T2D is the strongest predictor of more severe manifestations of NASH, namely advanced liver fibrosis, cirrhosis (including decompensation/liver failure), and HCC. Consequently, patients with these comorbidities represent a high-risk population, with NASH suspicion potentially suitable for screening.

In recent years, around the globe, many professional societies have started to explore and make recommendations to enhance the identification of patients with advanced fibrosis due to NASH. Examples include the EASL-EASD-EASO Clinical Practice Guidelines¹, Clinical Practice Guidance from the AASLD², ADA Standards of Medical Care in Diabetes³, and JSG-JSH Clinical Practice Guidelines⁴.

Appropriate suspicion, screening, identification, and linkage to care of patients with advanced fibrosis due to NASH remain a significant unmet need. Key success factors for identification of NASH patients and subsequent care delivery includes use of simple noninvasive tests (NITs), standardized referral and treatment algorithms, and multi-disciplinary collaboration between endocrinology/diabetology and hepatology/GI specialists.

Gilead seeks to support healthcare professionals from around the globe in their implementation and evaluation of innovative NASH models of care through this RFP program. In 2019, Gilead Medical Affairs team will launch its inaugural RFP program in **NASH Models of Care**, with an aim towards supporting projects focused on ways to develop efficient and effective care pathways between multidisciplinary providers in the screening, identification, referral and treatment of high-risk NASH patients.

Successful projects should demonstrate clear objectives, defined timelines, a scientifically appropriate care pathway plan (i.e., protocol), and proposed data generation which has relevance to the medical community and policy makers, focusing on:

- Implementation science evaluating screening for NASH in endocrinology/diabetology settings, with subsequent linkage to specialty care
 - Simplified approaches to identifying NASH patients at high-risk for advanced fibrosis, utilizing currently available and approved NITs
 - Innovative referral and treatment pathways for high-risk patients
 - Potential utilization of digital patient technology
 - Multidisciplinary care models for NASH patients with advanced fibrosis



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- Best Practices in NASH and institutional infrastructure
 - Facilitation of cross-departmental collaboration
 - Establishment of endocrinology/diabetology referral pathways
- Models of utilization of NITs in early identification of advanced fibrosis (F3/F4) due to NASH
 - Auto-calculation of FIB-4 within EMR, with referral prompts

The NASH Models of Care program aims to fund approximately 8-10 projects worldwide, with a total budget of US \$4M. Proposals greater than \$500,000 will be discussed with a Gilead Medical Scientist prior to submission.

Gilead retains the right to accept or deny any proposal and will attempt to ensure submissions fulfill a data need, and represent geographic distribution across the world.

Letter of Intent (LOI) should adhere to the following:

- Indirect (i.e., overhead) costs are \leq 30% of the requested funding
- Enrollment for the proposed study should be completed within 30 months
- Funding requests for sole purpose of screening costs will not be considered

Key Dates & Program Specifics

- **3 June 2019:** LOI submission window opens
 - **15 July 2019:** LOI submission window closes
 - LOI should be entered into the provided template, available at www.gilead.com/science-and-medicine/research/investigator-sponsored-research/nash-models-of-care-rfp and submitted to NASHModelsofCare@gilead.com
 - Proposals should not exceed 1,000 words
- After submission window closes, Gilead will evaluate and rank all LOIs. Top ranked LOIs will be invited to submit a full application. Based on prior programs, approximately 20% of LOIs are expected to be selected as full proposals and instructions will be provided.

Gilead plans to approve awards for these research proposals, dependent upon availability of funds and receipt of meritorious applications. Awards shall be for research purposes only.

Questions about the announcement or application process should be submitted to your local Gilead Medical Scientist. Applications are reviewed by an internal review committee.

About Gilead Sciences

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. The company strives to transform and simplify care for people with life-threatening illnesses around the world. Gilead has operations in more than 35 countries worldwide, with headquarters in Foster City, California.

1. EASL: European Association for the Study of the Liver; EASD: European Association for the Study of Diabetes; EASO: European Association for the Study of Obesity Clinical Practice Guidelines *J Hepatol* 2016;64:1388–1402
2. Chalasani N, et al. The Diagnosis and Management of Nonalcoholic Fatty Liver Disease: Practice Guidance From the American Association for the Study of Liver Diseases. *Hepatology*. 2018;67(1):328–357.



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3. American Diabetes Association. Standards of Medical Care in Diabetes – 2019. *Diabetes Care* 2019;42(Suppl 1).
4. Watanabe S, Hashimoto E, Ikejima K, Japanese Society of Gastroenterology. Japan Society of Hepatology Evidence-based clinical practice guidelines for nonalcoholic fatty liver disease/nonalcoholic steatohepatitis. *J Gastroenterol.* 2015;50:364–377. doi: 10.1007/s00535-015-1050-7