The attached document contains a new Request for Proposal (RFP) from Pfizer's Global Medical Grants program. While Pfizer recognizes many institutions and healthcare professionals around the globe are prioritizing challenges associated with the COVID-19 pandemic, we are cognizant that the healthcare and patient community will continue to benefit from ongoing support for research, improvement science, and education in spite of this crisis. It is in this spirit that Pfizer will continue our grants program by publishing RFPs that have been planned for 2020. Thank you in advance for all that you are doing to improve the care of patients. Pfizer is proud to be able to support these efforts through this grants program. Please contact the Global Medical Grants team at GMG@pfizer.com if you have any questions or would like to be temporarily removed from our mailing list.

Pfizer Announces

NASH – Future of Non-invasive Diagnosis Technologies

Competitive Grant Program - internal Pfizer review process

I. Background

Pfizer Global Medical Grants (GMG) supports the global healthcare community's independent initiatives (e.g., research, quality improvement, or education) to improve patient outcomes in areas of unmet medical need that are aligned with Pfizer's medical and/or scientific strategies.

Pfizer's GMG competitive grant program involves a publicly posted Request for Proposal (RFP) that provides detail regarding a general area of interest, sets timelines for review and approval, and uses an internal Pfizer review process to make final grant decisions. Organizations are invited to submit an application addressing the knowledge gaps as outlined in the specific RFP.

For all independent medical education grants, the grant requester (and ultimately the grantee) is responsible for the design, implementation, and conduct of the independent initiative supported by the grant. Pfizer must not be involved in any aspect of project development, nor the conduct of the independent education program.

II. Eligibility

Geographic Scope:	Global
Applicant Eligibility Criteria	• The following may apply: medical, dental, nursing, allied health, and/or pharmacy professional schools; healthcare institutions (both large and small); professional associations and medical societies; medical education companies; and other entities with a mission related to healthcare professional education and/or healthcare improvement. • If the project involves multiple departments within an institution and/or between different institutions / organizations / associations. All institutions must have a relevant role and the requesting organization must have a key role in the project. • For projects offering continuing education credit, the requesting organization must be accredited.

III. Requirements

Date RFP Issued	May, 2020
Clinical Area	Nonalcoholic steatohepatitis (NASH)
General Area of Interest for this RFP:	It is our intent to provide an independent grant(s) to an organization or organizations that will focus on the future of non-invasive diagnosis for nonalcoholic steatohepatitis (NASH). NASH is defined as the presence of ≥5% hepatic steatosis and inflammation with hepatocyte injury with or without fibrosis.[1,2] Currently, liver biopsy remains the gold standard for the diagnosis of NASH, however, many healthcare providers do not recommend it to their patients due to associated risks and limitations.[1, 3] Liver biopsy is an invasive procedure that is expensive, carries potential for sampling error, requires interpretation from expert pathologists, and has some morbidity and mortality risk.[3,4] Consequently, it is not used widely in clinical practice and is reserved for patients who are most at risk and would benefit from a diagnosis of NASH.[5] As research on NASH treatments evolves, it is critical that patients are rapidly and efficiently identified and diagnosed. There is an unmet need for non-invasive diagnostic tools and biomarkers for NASH that can quickly and easily diagnose the severity of NASH, monitor liver changes, and identify high risk patients. These tools will help to predict which patients are at greatest risk of developing NASH, and how rapidly their disease will likely progress. One goal in accelerating innovations in NASH diagnosis is

	identifying non-invasive biomarkers and tools that deliver high precision and specificity to properly diagnose, prognose and monitor the disease and that can be easily applied in clinical practice at a low cost. The submitted proposals should aim to inform the scientific and clinical community and to advance the discussion around non-invasive biomarkers and diagnostic tools for NASH. Multiple paths can be deployed to inform the future of non-invasive diagnosis for NASH. For example, both an in-depth literature search and insights gathered from a meeting of experts could identify non-invasive biomarkers and tools with the highest potential of being applied in clinical practice in the near and distant future. A publication to communicate the outcome of this data is encouraged to advance the discussion among a broader scientific and clinical audience. References: 1. 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 Jan;67(1):328-357 2. Yeh MM, Brunt EM. Pathological features of fatty liver disease. Gastroenterology 2014;147:754-764. 3. Sumida Y, Nakajima A, Itoh Y. Limitations of liver biopsy and non-invasive diagnostic tests for the diagnosis of nonalcoholic fatty liver disease/nonalcoholic steatohepatitis. World J Gastroenterol. 2014;20(2):475-485. 4. Bravo AA, Sheth SG, Chopra S. Liver biopsy. N Engl J Med 2001;344:495-500. 5. Brunt EM, Neuschwanter-Tetri BA, Burt AD. Fatty liver disease: alcoholic and non-alcoholic. Burt AD, Portmann B, Ferrell K (Eds.), MacSween's pathology of the liver (6th ed), Churchill Livingstone Elsevier, Edinburgh (2012), pp. 293-359.
Target Audience:	Specialists, scientific researchers, and other healthcare professionals
Expected Approximate Monetary Range of Grant Applications:	Individual projects requesting up to $250,000 USD will be considered.
Key Dates:	• RFP release date: April 22, 2020 • Grant Application due date: July 30, 2020 Please note the deadline is midnight Eastern Standard Time (e.g. New

	York, GMT -5). • Anticipated Grant Award Notification Date: August 2020 • Grants will be distributed following a fully executed agreement. • Anticipated Project Start: August/September 2020

How to Submit:	• Please go to www.cybergrants.com/pfizer/knowledge and sign in. First-time users should click "Create your password".
	• In the application:
	  ○ For the question "What type of request are you submitting?" select Response to a Request for Proposal (RFP)
	  ○ For the question "Are you replying to a Request for Proposal as part of the Competitive Grant Program?" select Yes
	  ○ Select the following Competitive Grant Program Name: NASH Diagnosis
	  ○ Select the following Primary Area of Interest: NASH
	• Requirements for submission:
	Complete all required sections of the online application and upload your project proposal (see Appendix) in the General RFP Submission field.
	• If you encounter any technical difficulties with the website, please click the "Technical Questions" link at the bottom of the page.
	IMPORTANT: Be advised applications submitted after the due date will not be reviewed by the committee.

Questions:	• If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Angelo Carter (angelo.carter@pfizer.com), with the subject line "2020 NASH Diagnosis"
Mechanism by which Applicants will be Notified:	• All applicants will be notified via email by the dates noted above. • Applicants may be asked for additional clarification during the review period.

IV. Terms and Conditions

Please take note every RFP released by Pfizer Global Medical Grants (GMG) is governed by specific terms and conditions. These terms and conditions can be reviewed here.

Appendix A

General RFP Submission Requirements

Project Proposals should be single-spaced using Calibri 12-point font and 1-inch margins. Note there is a 15-page limit exclusive of references. Please include the following:

Goals and Objectives	• Briefly state the overall goal of the project. • List the objectives you plan to meet with your project, in terms of learning and expected outcomes.
Needs Assessment for the Project	• Include a description of your organization's needs assessment for this proposed project which may include a quantitative baseline data summary, initial metrics, or a project starting point (please cite data on gap analyses or relevant patient-level data that informs the stated objectives) in your target area.
Target Audience	• Describe the primary audience(s) targeted for this project. Indicate whom you believe will directly benefit from the project outcomes. Describe the overall population size as well as the size of your sample population.
Project Design and Methods	• Describe the planned project, the educational approach, and the way the planned methods address the established need.
Innovation	• Explain what measures you have taken to assure that this project is original and does not duplicate other projects or materials already developed. Describe how this project builds upon existing work, pilot projects, or ongoing projects developed either by your institution or other institutions.
Evaluation and Outcomes	• In terms of the metrics used for the needs assessment, describe how your organization will determine if the gap was addressed for the target group. Identify the sources of data your organization anticipates using to make the determination. Describe how your organization is expected to collect and analyze the data. Explain the method used to control for other factors outside this project (e.g., use of a control group or comparison with baseline data). Quantify the amount of change expected from this project in terms the target audience. Describe how your organization will determine if the target audience was fully engaged in the project.
Dissemination Plan	• Describe how the project may have extended benefit beyond the grant. Will the teaching materials be made available to others to use? Will there be tools or resources that are made publicly available beyond the initial project. Describe how the project outcomes might be broadly disseminated.

Anticipated Project Timeline	• Provide an anticipated timeline for your project including project start/end dates.
Additional Information	• If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please summarize here.
Organization Detail	• Describe the attributes of the institutions/organizations that will support and facilitate the execution of the project, the leadership of the proposed project, and the specific role of each institution in the proposed project.

Budget Narrative	• Please include a budget narrative that describes in greater detail the line items specified in the budget submitted within the application
	• While estimating your budget please keep the following items in mind:
	  ○ Independent Medical Education Grants awarded by GMG cannot be used to purchase therapeutic assets (prescription or non-prescription).
	  ○ Overhead rates of up to 28% of the total proposed project budget may be supported by Pfizer.