Next Generation Imaging Using Serial ^{18}F-flutemetamol PET to Assess Diagnostic Performance and/or Disease Stabilization in Patients with Transthyretin Amyloid Cardiomyopathy (ATTR-CM) Treated with Tafamidis

Research Competitive Grant Program - Request for Proposals (RFP)

Introduction

GE Healthcare and Pfizer are collaborating to offer a new competitive grant opportunity focused on addressing diagnostic performance and disease stabilization using ^{18}F-flutemetamol cardiac PET in subjects presenting with ATTR-CM and are treated with Tafamidis.

GE Healthcare's Pharmaceutical Diagnostics unit develops and supplies imaging agents used to support around 100 million procedures per year globally, equivalent to three patients every second.

GE Healthcare is the $16.7 billion healthcare business of GE (NYSE: GE). As a leading global medical technology and digital solutions innovator, GE Healthcare enables clinicians to make faster, more informed decisions through intelligent devices, data analytics, applications and services, supported by its Edison intelligence platform. With over 100 years of healthcare industry experience and around 50,000 employees globally, the company operates at the center of an ecosystem working toward precision health, digitizing healthcare, helping to drive productivity and improve outcomes for patients, providers, health systems and researchers around the world.

The mission of Pfizer Global Medical Grants is to accelerate the translation of science into quality patient care through independent grants, partnerships, and collaborations. Pfizer Global Medical Grants 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.

For all Investigator Sponsored Research (ISRs) and general research grants, the grant requester (and ultimately the grantee) is responsible for the design, implementation, sponsorship, and conduct of the independent initiative supported by the grant, including compliance with any regulatory requirements. Pfizer and GE Healthcare will not be involved in any aspect of study protocol or project development, nor the conduct or monitoring of the research program.

This Request for Proposals (RFP) is being issued by both organizations. A review committee which will include 1 Pfizer representative, 1 GE Healthcare representative and 3 external experts will make decisions on which proposals will receive funding. **Grant funding and overall management of the funded studies will be provided directly from Pfizer. Radiotracer will be provided directly from GE Healthcare through their manufacturing partner.**

[1] ^{18}F-flutemetamol has not be approved for cardiac PET imaging. Please click here for important safety information

Competitive Grant Program Eligibility

Geographic Scope	• United States
Applicant Eligibility Criteria	To be eligible: • **Please e-mail amanda.j.stein@pfizer.com to confirm eligibility and radiopharmaceutical availability** • The institution and principal investigator (PI) must be based in one of the eligible countries noted above. • Only organizations are eligible to receive grants, not individuals or medical practice groups. • The applicant (PI) must have a medical or postdoctoral degree (MD, PhD, or equivalent). • Applicant must be affiliated with a host institution

Requirements

Date RFP Issued	• October 6th, 2020
Clinical Area	• Advanced Cardiac Imaging, Transthyretin Cardiac Amyloidosis, PET
Area of Interest Focus	• Amyloid **PET** tracers such as **^{18}F-flutemetamol** could be a promising tool in the diagnosis and/or therapeutic response for patients with cardiac amyloidosis.[1] However, further data is needed to define the overall performance and additive value to current standard of care diagnostics in the care of patients with suspected systemic and/or ATTR cardiac amyloidosis.[2] Through this Research RFP, Pfizer and GE Healthcare wish to support research projects focused on assessing both diagnostic performance and changes over time of **^{18}F-flutemetamol** cardiac uptake after initiation of Tafamidis treatment in subjects diagnosed with ATTR cardiac amyloidosis. Collaborations within institutions (e.g., between departments and/or inter-professional), as well as between different institutions / organizations / associations, are encouraged. Please note all partners must have a relevant role and the requesting organization must have a key role in the project.

Expected Approximate Monetary Range of Grant Applications	• Individual projects requesting up to $125,000 will be considered. Pfizer and GE Healthcare anticipate awarding up to 2 grant(s).
Key Dates	• RFP release date: October 6th, 2020 • Application Submission Deadline: February 1st, 2021 **(Deadline Extended)** • Review of Applications by ERP: March 2021 [updated] • Anticipated Full Proposal Notification Date: April 2021 [updated]
How to Apply	• Please go to www.cybergrants.com/pfizer/Research and sign in. First-time users should click "Create your password". Requirements for submission: • Select the following Competitive Grant Program Name: 2020 RD US-Next Generation PET Imaging for ATTR-CM • When requesting Radiotracer as part of your project, please select the **Invited** option from the "Primary Pfizer Drug" list. A free text field will display, in this field enter **GE Healthcare/ F-flutemetamol**. • Complete all required sections of the online application. See Appendix A for additional details • If you encounter any technical difficulties with the website, please click the "Technical Questions" link at the bottom of the page
Questions:	• If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Amanda Stein (amanda.j.stein@pfizer.com), with the subject line "Next Generation PET Imaging for ATTR-CM." • Please click here to view Frequently Asked Questions regarding the Competitive Grant Program
Review and Approval Process	• Grant requests received in response to a specific RFP are reviewed by an expert review panel (ERP) to make final grant decisions. • The panels are comprised of professionals from the medical community with advanced degrees and expertise in nuclear cardiology and cardiac amyloidosis.
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

References:

1. Dietemann S, Nkoulou R. Amyloid PET imaging in cardiac amyloidosis: a pilot study using ^{18}F-flutemetamol positron emission tomography. *Ann Nucl Med*. 2019;33(8):624-628. doi:10.1007/s12149-019-01372-7
2. Gallegos C, Miller EJ. Advances in PET-Based Cardiac Amyloid Radiotracers. *Curr Cardiol Rep*. 2020;22(6):40. Published 2020 May 19. doi:10.1007/s11886-020-01284-3

Appendix A

Full Proposal/Protocol

Applications will be accepted via the online portal. Full Proposal/Protocol documents should be no longer than 10-15 pages in length (12-point font and 1-inch margins) excluding Organization Detail and References. When uploading your Full Proposal/Protocol please ensure it addresses the following:

Goals and Objectives	• Provide the main goal of the study and the study population (if applicable). Provide a detailed definition that is directly linked to the primary objective
Assessment of Need for the Project	• This should reflect your study rationale. Provide a brief description of the medical/scientific question and the rationale of how this trial or study addresses the question
Target Audience	• Describe the primary audience(s) targeted for this project. For Investigator Sponsored Clinical Trials, please specify the age, gender and other demographic information for trial population • Also 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 concisely the research design and methods for achieving the stated goals. For a clinical interventional study, include inclusion/exclusion criteria, treatment plan and statistical plan
Innovation	• Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects. Describe how this project builds upon existing work, pilot projects, or ongoing projects developed either by your institution or other institutions related to this project
Evaluation and Outcomes	• Specify type and frequency of safety, efficacy, and/or outcome measures. Also indicate the method(s) used to assess measures • Provide a publication plan describing intended submission of abstracts to

	(a) congress(es) or intended submission of (a) publication(s) to peer-reviewed journals. All publications must follow ICH guidelines
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 • Early-career applicants: Letter(s) of support from mentor(s) and collaborators describing how the award will advance the applicant's career.
Organization Detail	• This information is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be used [laboratory, animal, clinical and "other"]. If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project
References	• Bibliography of relevant references.