Approaches to Increase Equitable Access to and Delivery of Quality of Care with Bispecific Antibodies for Patients with Multiple Myeloma Request for Proposals (RFP)

1.Introduction

The International Myeloma Foundation (IMF) and Pfizer are pleased to collaborate to offer a grant opportunity to support Quality Improvement (QI) projects that will advance the quality of care and best practices around treatment for patients with relapse/refractory multiple myeloma (RRMM) receiving treatment with a bispecific antibody (BsAb).

About the International Myeloma Foundation

The International Myeloma Foundation (IMF) is the first and largest global organization focusing specifically on multiple myeloma. The IMF is dedicated to improving the quality of life of myeloma patients while working toward prevention and a cure through our four founding principles: Research, Education, Support, and Advocacy.

About Pfizer Global Medical Grants

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 specific area of interest, sets timelines for review and approval, and uses an expert review panel (ERP) to make final grant decisions. Organizations are invited to submit an application addressing the specific gaps in practice as outlined in the specific RFP.

For all quality improvement 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 or monitoring of the quality improvement program.

This RFP is being issued by both organizations. The IMF is the lead organization for review and evaluation of proposals. A review committee, led by the IMF, will make decisions on which proposals will receive funding.

2.Background

Through a mutual desire to close gaps in care for myeloma patients, Pfizer and IMF have jointly issued this RFP seeking proposals to improve quality through standardization of processes and education to reduce variability in outcomes where bispecific antibodies are utilized as a treatment in the community.

A successful project will incorporate quality improvement methods to overcome identified barriers to improve care. These barriers include, but are not limited to, identifying clinical and treatment related factors, patient-related psychosocial factors, racial and ethnic factors, socioeconomic factors, and healthcare system or technological related barriers to patient care.

Quality improvement considers aspects of quality such as clinical competence, outcomes and process assessment, program evaluation, quality indicators and quality assurance. Quality improvement grants help improve patient outcomes in areas of unmet medical needs. They should not be confused with

general research grants which are focused on the development or refinement of specific and defined medical knowledge. Research projects answer questions about best practice, whereas Quality Improvement projects implement best practices.

Bispecific antibodies are novel immunotherapies that are both FDA-approved and under investigation in patients with multiple myeloma. They appear to have an acceptable safety profile and promising efficacy, with the further potential benefit of being "off-the-shelf". However, logistical coordination of care is a potential learning curve as these treatments transition to real-world and outpatient settings. Additionally, there will be a need to educate health care teams, patients, and care partners regarding post-administration monitoring and to collaboratively manage side effects. A need may exist around potentially expanding the care team to consider the prevention, early identification, and management of side effects, including cytokine release syndrome (CRS), neurotoxicity, infection risk. Additionally, the introduction of these novel bispecific antibodies creates a need to standardize coordination of care and share best practices among community centers. Finally, there will be logistical considerations in ensuring equitable access to all people with myeloma, such that outcomes are optimized for all, whether disparities arise for reasons of geography, finances, or race.

3.**Eligibility**

Geographic Scope:	Global
Eligibility Criteria:	• Academic, Community Cancer Centers, and healthcare systems (Principal Investigators from Academic Centers are encouraged to include a co-investigator from the community) • Patient Advocacy Groups • Health care professional organizations and other organizations with a mission related to health care improvement • Health technology companies must partner with a health care delivery organization and the health care delivery organization must be the lead applicant

4.**Proposals**

Applicants are invited to submit a detailed quality improvement proposal into Pfizer's web-based system by June 1, 2023 (see Section 7 Submission Requirements). **Researchers seeking funding for therapeutic clinical trials projects will not be considered under this RFP.**

5.**Requirements**

Date RFP Issued:	3/31/2023
Clinical Area:	Relapsed/Refractory Multiple Myeloma
Areas of Interest for this RFP:	The intent of this Request for Proposal (RFP) is to support Quality Improvement initiatives that will increase equitable access to and delivery of quality care for patients with multiple myeloma in the community. **Proposals in the following topic areas are strongly encouraged:** • Ensuring continuity of care in patients receiving bispecific antibodies for RRMM throughout the entirety of their care journey, including managing transitions of care from the inpatient to outpatient setting • Establishing a process for Adverse Events (AE) management and reporting (including training and anticipating, identifying, and managing AEs) • Local or regional projects that identify areas for systematic improvement and implementing customized/data driven solutions • Improving processes for enabling equitable access to bispecific antibodies regardless of geography, race, or financial status • Establish expert mentoring and support system between academic and community centers to ensure appropriate patient selection and therapy management with a bispecific antibody • Ways to increase enrollment and retention in Clinical Trials with a particular focus on under-represented populations. • Innovative approaches to promote effective communication between members across the care continuum (e.g., decision- making, care planning, and/or patient monitoring). This includes community health workers, social needs navigators, or other means, that connect patients to community-based organizations and resources (especially in practices serving low-income and/or socially vulnerable patient populations). • Novel technology solutions to improve the care of MM patients, including remote monitoring solutions. • HCP education addressing bispecific antibody therapy management, with focus on AE's of special interest such as CRS, ICANS, infections

Areas of Interest for this RFP (continued):	In addition to the topic areas above, we encourage all applicants to include a component that addresses disparities in access to equitable care within their proposal. Furthermore, we encourage applicants to consider partnering with IMF as a strategy to accomplish the goals of the project. **Proposals in the following topic areas will be considered out-of-scope for this RFP:** • Clinical trials investigating new drug entities. • Clinical trials comparing drug entities.
Geographic Scope:	• Global
Target Audience for the QI initiatives:	• Practicing HCPs and researchers. • Patients with MM and their caregivers.
Expected Approximate Monetary Range of Grant Applications:	• There is at least $1,250,000 for funding of all projects. • The intent is to fund individual projects capped at $250,000 (direct and indirect costs) although smaller, lower-costs projects are encouraged. Funding greater than $250,000 will be considered for exceptional proposals with detailed budget justification. • The maximum indirect (overhead) rate is 28% and must be included in the total grant request amount. Indirect costs examples are noted in section 7 below. • Applicants are required to disclose additional sources of funding for this project and demonstrate that funding does not overlap.
Key Dates:	• RFP release date: March 31, 2023 • Full Proposal Submission Deadline: June 1, 2023 Please note the deadline is 5:00 pm Eastern Time • Anticipated Grant Award Notification Date: July 30, 2023 • Grants will be distributed in-full following execution of a Letter of Agreement and documentation of an IRB approval or waiver. **IRB approval or waiver must be received by December 31, 2023 or risk grant cancellation.** • Period of Performance: December 2023 to December 2025 (projects may be shorter; 2-year project maximum)

Questions:	• If you have questions regarding this RFP, please direct them in writing to Haleigh Wolfe at hwolfe@myeloma.org for IMF related questions or Pfizer's Grant Officer, Amanda Kaczerski at Amanda.Kaczerski@pfizer.com with the subject line "**March 2023 Pfizer IMF MM Quality Initiative"**.

How to Submit:	• Please go to www.cybergrants.com/pfizer/QI and sign in. First-time users should click "REGISTER NOW".
	• Select the following Competitive Grant Program Name: **2023 Onc G IMF MM QI RFP**
	• Select the following Area of Interest: **Oncology – Hematologic**
	• Requirements for submission:
	  • Complete all required sections of the online application referring to the guide included in the Appendix.
	  • If you encounter any technical difficulties with the website, please click the "Need Support?" link at the bottom of the page.
	IMPORTANT: Be advised applications submitted through the wrong application type and/or submitted after the due date will not be reviewed by the committee.

Review and Approval Process:	• The IMF and Pfizer developed this RFP and the IMF has independently established an external Scientific Review Committee to determine funding decisions. This external peer review will utilize a formal process to evaluate and select proposals of the highest scientific merit. One representative from Pfizer will participate in the review.
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.

6.**Terms and Conditions**

1. This RFP does not commit Pfizer or their partners to award a grant or a grant of any particular size if one is awarded, nor to pay any costs incurred in the preparation of a response to this request.

2. If your grant is approved, your institution will be required to enter into a written grant agreement with Pfizer. Please click here to view the core terms of the agreement. These terms have been drafted to be balanced and reasonable and to further the goals of both parties. Negotiating grant agreements requires significant resources, so please ensure that your institution (including your legal department) is able and willing to abide by these terms before proceeding with submission of your application as they will need to be accepted in their entirety.

3. This RFP is supported by Pfizer Inc. and, if approved, payment will be sent from the United States.

4. Payment will only be made to requesting Institution.

7.**Submission Requirements**

Applications will be accepted via the online portal listed in the How to Submit section. Full Proposal 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 please ensure it addresses the following*:

Goals and Objectives	Briefly state the overall goal of the project. Describe how this goal aligns with the focus of the RFP and the goals of the applicant organization(s). List the *overall* objectives you plan to meet with your project both in terms of learning and expected outcomes. Objectives should describe the target population as well as the outcomes you expect to achieve as a result of conducting the project.
Assessment of Need for the Project and Preliminary Data	Please include a quantitative baseline data summary, initial metrics (e.g., quality measures), 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. Describe the source and method used to collect the data. Describe how the data was analyzed to determine that a gap existed. If a full analysis has not yet been conducted, please include a description of your plan to obtain this information.
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 and the way it addresses the established need. If your methods include educational activities, please describe succinctly the topic(s) and format of those activities.

Innovation	Explain what measures you have taken to assure that this project idea 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 related to this project.
Evaluation and Outcomes	In terms of the metrics used for the needs assessment, describe how you will determine if the practice gap was addressed for the target group. Describe how you expect to collect and analyze the data. Quantify the amount of change expected from this project in terms of your target audience. Describe how the project outcomes will be broadly disseminated.
Health Equity	Explain how the project helps reduce health disparities in MM
IMF Partnership	Discuss how the project may partner with the IMF to meet its objectives
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 the reviewers should be aware of concerning the importance of this project, please summarize here.
Organization Detail **(Environment and Mentors)**	Describe the attributes of the institutions/organizations/associations that will support and facilitate the execution of the project and the leadership of the proposed project. Articulate the specific role of each partner in the proposed project. Letters of support from partner organizations are required to be submitted with the full proposal.

Budget Detail	The budget amount requested must be in U.S. dollars (USD). While estimating your budget please keep the following items in mind: Institutional overhead and indirect costs may be included within the grant request. Examples include human resources department costs, payroll processing and accounting costs, janitorial services, utilities, property taxes, property and liability insurance, and building maintenance as well as additional project expenses such as costs for publication, IRB/IEC review fees, software license fees, and travel. Please note: Pfizer does not provide funding for capital equipment. The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP. It should be noted that grants awarded through GMG cannot be used to purchase therapeutic agents (prescription or non-prescription). Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects. Please click here for details.