Approaches to Implement Bispecific Antibodies into Clinical Practice, Increase Awareness and Improve Delivery of Quality of Care for Patients with Multiple Myeloma – Request for Proposals (RFP)

1.Introduction

Myeloma Canada and Pfizer Canada 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 relapsed/refractory multiple myeloma (RRMM) receiving bispecific antibody (BsAb) treatment.

About Myeloma Canada

Myeloma Canada is the only national charitable organization created by, and for, Canadians impacted by multiple myeloma. The organization is driven to improve the lives of those affected by myeloma by empowering the community through awareness, education and advocacy programs, and supporting clinical research to find a cure. Since it was founded in 2005, Myeloma Canada has been making myeloma matter. Learn more here: www.myeloma.ca.

Our promise: To improve the lives and empower all Canadians affected by myeloma, accelerate access to the best care, while supporting the pursuit of its cure and prevention.

About Pfizer Global Medical Grants

Pfizer Global Medical Grants (GMG) supports the global healthcare community's independent initiatives (e.g., research, QI 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 QI 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 QI program.

This RFP is being issued by both organizations. Myeloma Canada is the lead organization for review and evaluation of proposals. A review committee, led by Myeloma Canada, 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 Myeloma Canada are jointly issuing this RFP seeking proposals to improve quality through standardization of processes and education to reduce variability in outcomes where BsAbs may be utilized as a treatment for patients with Multiple Myeloma.

A successful project will incorporate QI methods to overcome identified barriers to improve care, as well as health care professional (HCP) education pertaining to evidence and recommendations in the management of BsAb treatment. These barriers include, but are not limited to, clinical and treatment related factors, patient-related psychosocial factors, socioeconomic or geographic factors, and healthcare system or technological related barriers to patient care.

QI considers aspects of quality such as clinical competence, outcomes and process assessment, program evaluation, quality indicators and quality assurance. QI 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 QI projects implement best practices.

Multiple myeloma is a cancer of the bone marrow plasma cells. In myeloma, abnormal plasma cells (also known as myeloma cells) interfere with the production of normal healthy blood cells in the bone marrow and overproduce inactive clones of abnormal antibodies that can negatively affect different parts of the body such as the bones and kidneys. Multiple myeloma is the second most common blood cancer. According to the Canadian Cancer Statistics 2022, the number of new myeloma cases diagnosed in 2022 were estimated at 4,000. Approximately 11 people are diagnosed with myeloma in Canada each day.

BsAbs are novel immunotherapies under investigation in patients with multiple myeloma in Canada. Growing evidence has revealed impressive efficacy and a manageable safety profile with BsAbs in the treatment of multiple myeloma. One distinguishing feature of the BsAbs is their ability to be used “off-the-shelf”, not needing to be engineered for each patient. Integration of these novel therapies, while promising, may pose many challenges to the healthcare systems, healthcare teams, and patients. Potential areas of challenge may include coordination of care, transition of care from in-patient to outpatient settings or from academic to community settings, and monitoring and managing side effects. There may be a need to expand the care team to consider the prevention, early identification, and management of side effects, including cytokine release syndrome (CRS), neurotoxicity, infection risk. Additionally, healthcare providers and patients will need education about potential new treatment options and potential side effect monitoring and management. Ultimately there is a need to identify standardized processes and education that will result in optimized patient care that will overcome disparities (geographic, racial, financial) and provide equitable access to effective therapy. Sharing of best practices among both academic and community centres will also be an important consideration as BsAbs enter real-world outpatient settings.

3. **Eligibility**

Geographic Scope:	Canada
Eligibility Criteria:	• Academic, Community Cancer Centres, and healthcare systems (Principal Investigators from Academic Centres are encouraged to include a co-investigator from the community) • Healthcare professional organizations and other organizations with a mission related to healthcare improvement • Health technology companies must partner with a healthcare delivery organization and the healthcare delivery organization must be the lead applicant • If the project involves multiple departments within an institution and/or between different institutions/organizations/associations, all departments/institutions/organizations/associations must have a relevant role and the requesting organization must have a key role in the project

4.**Proposals**

This RFP is seeking request for QI projects. It is not our intent to support research projects. Research projects will be considered out of scope for this project. Examples of out-of-scope projects include clinical research projects, basic science research, prevalence studies, registry development, health services research and outcomes research.

5.**Requirements**

Date RFP Issued:	March 15, 2023
Clinical Area:	Relapsed/Refractory Multiple Myeloma
Areas of Interest for this RFP:	The intent of this RFP is to support QI initiatives that will increase equitable access to and delivery of quality care for patients with multiple myeloma with the goal of optimizing the care and outcomes of patients. **Proposals in the following topic areas are strongly encouraged:** • Support for clinicians on topics such as treatment selection, emerging novel mechanism of action (MOA) of BsAbs, and therapy and patient management • Strategies for coordinating BsAb therapy management between oncologists and the multidisciplinary and multispecialty care team • Transition of care from in-patient to out-patient setting and therapy scheduling, dosing, and management of side effects • Adverse event (AE) management-training and processes for how to anticipate, mitigate and manage adverse events associated with BCMA-directed antibodies in RRMM • Multi-disciplinary care models (e.g., nurse navigator, oncology nurse) • Methods for addressing disparities (geographic, racial, financial) and access to care • Integration of strategies to improve health literacy for the patient throughout their cancer journey • HCP Education addressing BsAb therapy management, with focus on AEs of special interest such as CRS, immune effector cell-associated neurotoxicity syndrome (ICANS), infections

Areas of Interest for this RFP (continued):	**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 • Clinical research projects, basic science research, prevalence studies, registry development, health services research and outcomes research
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 $250,000 available for funding of all projects. • The intent is to fund individual projects capped at $100,000 (direct and indirect costs) although smaller, lower-costs projects are encouraged. Funding greater than $75,000 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. • Applicants are required to disclose additional sources of funding for this project and demonstrate that funding does not overlap. • The decision relative to funding is deferred to the members of the Scientific Review Committee (SRC) as chosen by Myeloma Canada.
Key Dates:	• RFP release date: March 15, 2023 • Full Proposal Submission Deadline: June 1, 2023 • 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.** • Period of Performance: October 2023 to October 2025 (projects may be shorter; 2-year project maximum)

Questions:	• If you have questions regarding this RFP, please direct them in writing to Myeloma Canada's Director of Science & Research, Gabriele Colasurdo at gcolasurdo@myeloma.ca or Pfizer's Grant Officer, Amanda Kaczerski at Amanda.Kaczerski@pfizer.com with the subject line "**March 2023 Pfizer Myeloma Canada Quality Improvement"**.

How to Submit:	• Please go to https://www.cybergrants.com/pfizer/QIand sign in. First-time users should click "REGISTER NOW".
	• Select the following Competitive Grant Program Name: **2023 ONC Canada Myeloma Quality Improvement**
	• 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:	• An expert review panel has been formed to oversee this process and will utilize a formalized review procedure to select the proposals of highest scientific merit. Myeloma Canada oversaw the development of this RFP and the expert review panel will perform the peer review of applications.
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.

7.**Submission Requirements**

Applications will be accepted via the online portal. 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.
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 Canadian dollars (CAD). 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.