Pfizer Canada, Colorectal Cancer Canada and ThermoFisher Scientific Quality Improvement Initiative:

2023 Oncology Precision Medicine QI: Implementing Rapid Turnaround Time for NGS Molecular Testing for Cancer Patients in Non-Academic and Community Centres

Introduction & Background

Colorectal Cancer (CRC) is the second most fatal form of cancer for men and third most fatal form of cancer for women in Canada (Brenner, Darren R., et al. “Projected estimates of cancer in Canada in 2022.” CMAJ 194.17 (2022): E601-E607). In recent years, the systemic therapy management of metastatic colorectal cancer (mCRC) has evolved from primarily cytotoxic chemotherapies to now include precision medicine where the molecular profiling of the disease can alter treatment strategies and can improve clinical outcomes for some patients.

Implementation of point of care molecular testing and rapid turnaround time for the reporting of biomarker results are critical to the effective integration of precision medicine in the cancer patient care plan. A recent Canadian initiative has demonstrated the feasibility of implementing rapid NGS testing in a Canadian community centre using highly automated gene sequencing systems that can be used within a diagnostic histopathology laboratory in tandem with diagnostic and predictive IHC assays, eliminating transfers of specimens and reports (Sheffield, Brandon S., et al. "Point of care molecular testing: community-based rapid next-generation sequencing to support cancer care.” Current Oncology 29.3 (2022): 1326-1334). This groundbreaking project also demonstrated an important impact in delivery of biomarker testing results, with a significant reduction of turnaround time to less than 7 days (Sheffield, Brandon S., et al. “Point of care molecular testing: community-based rapid next-generation sequencing to support cancer care.” Current Oncology 29.3 (2022): 1326-1334).

Pfizer Canada (Pfizer), Colorectal Cancer Canada (CCC) and Thermo Fisher Scientific (TFS) are collaborating to offer a new funding opportunity seeking proposals for quality improvement (QI) initiatives focusing on empowering Canadian centres without in-house molecular testing capacity. This QI initiative aims to improve molecular testing turnaround time for patients with colorectal cancer (CRC) and other tumour types. In this Request for Proposals (RFP), applicants are encouraged to review and consider the **Funding Opportunities** described below to support and develop their innovative ideas aimed at streamlining molecular testing processes, for example: targeting “bottle-necks” in testing workflow, including integration of in-house NGS testing at the applicants’ centre. Funding and general oversight of the funded projects will be provided directly from Pfizer on behalf of the collaborators. Applicants are encouraged to showcase how their ideas can have sustainable and measurable impact on molecular testing turnaround time, and by extension on cancer care for patients in Canada.

> **Pfizer’s Global Medical Grants (GMG)** program 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.
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> **Colorectal Cancer Canada (CCC)** is a patient association dedicated to colorectal cancer awareness and education, support for patients and their caregivers, and

advocacy on their behalf and aspires to reduce the incidence and mortality of colorectal cancer in Canada while improving the quality of life of patients, their families and their caregivers. Founded in 1998, CCC celebrates this year twenty-five years of advocacy on behalf of Canadian CRC patients. Through the Get Personal project and numerous other educational initiatives, CCC has prioritized the improvement of timely access to molecular testing for Canadian mCRC patients among its many important objectives.

Thermo Fisher Scientific (TFS) is a world leader in serving science, with the mission to enable their customers to make the world healthier, cleaner, and safer. Oncomine Solutions for Next-Generation Sequencing is an integrated next-generation sequencing-based approach that intends to advance precision oncology from research to real-world practice. Integration of Oncomine Solutions in pathology practice allows cancer care teams to provide molecular insights that inform the most critical decisions, and realize the promise of precision oncology. https://www.oncomine.com/

For all QI proposals, 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. **The collaborators must not be involved in any aspect of project development or implementation.**

Grants will be awarded in support of organizations/institutions working to improve the competence and performance of both the healthcare providers and healthcare systems in which they work with the goal of optimizing the care and outcomes of cancer patients.

Funding Opportunities:

The intent of this RFP is to encourage Canadian centres, especially non-academic or community institutions, to submit a quality improvement project that aims to achieve rapid turnaround time for NGS-based advanced molecular testing for patients in CRC and other cancer types, including but not limited to introduction of in-house NGS testing. Applicants are invited to implement innovative ideas with the goal of creating a path for sustainable rapid turnaround molecular testing for cancer patients in Canada.

- Applicants must submit a QI project budget for a maximum of $100,000 CAD.
- Applicants from centres with readiness to implement in-house NGS testing workflow may include a request for a one-year lease for an NGS Sequencing System package to Thermo Fisher as part of their QI proposal*:
    - Up to an additional $100,000 CAD is available via this RFP to be used for this optional one-year lease. *In this case, t*he maximum total request for the QI proposal will be $200,000 CAD.
    - Applicants may include NGS consumables and reagents as part of the project budget. Applicants must contact Thermo Fisher for further details (Nelson Ho nelson.ho@thermofisher.com).

Following completion of the QI project period, and in line with long-term sustainability goals of this effort, recipient(s) of the leased instrumentation will receive the option to purchase the NGS Sequencing System at Fair Market Value or through a lease extension of up to four additional

years. Applicants must contact Thermo Fisher for further details (Nelson Ho nelson.ho@thermofisher.com).

*Applicants will need to demonstrate capacity to run immunohistochemistry (IHC)-based point of care molecular pathology workflow to qualify for this offering.

Geographic Scope:

- Canada

Eligibility and Applicant Criteria:

Applicants are encouraged to use a multidisciplinary care model (e.g., pathologist, medical oncologist, surgeon, researcher, etc.). All partners must have a relevant role and the requesting organization must have a key role in the project.

- Only organizations are eligible to receive grants, not individuals or medical practice groups.
- Applicant must be collaborating with an accredited pathology practice in Canada.
- Centres that do not currently have the capacity for, or do not have validated in-house molecular testing (i.e., require instrumentation, training, and / or other resources), are eligible.
- The following may apply: medical schools; healthcare institutions (both large and small); professional associations; government agencies; and other entities with a mission related to healthcare improvement.
- Project duration is expected to be up to 24 months.

Clinical Area:

Colorectal cancer (CRC): all disease stages

- All projects must include a component that addresses quality improvement for CRC patients
- In addition to CRC, applicants may submit project proposals that also encompass other tumour types (for example: lung cancer, breast cancer or others with important unmet needs in molecular testing).

Specific Area of Interest for this RFP#:

Applicants are encouraged to include in their QI proposals their dissemination plan for their project findings, for example: conference abstract submission, publication in a peer-reviewed journal…etc.

Topics of highlighted interest include, but are not limited to:

- Achieving rapid turnaround time for molecular testing for cancer patients (including but not limited to CRC as described above in **Clinical Area**)
- Non-academic / community centres that aim to achieve access to in-house molecular testing by targeting barriers to NGS integration into current workflow.
- Academic centres without in-house NGS molecular testing capacity and innovative approaches to molecular testing sustainability will be considered.
- Creating a sustainable workflow and operation based on the applicant institutional needs, for example: training, instrument implementation…etc.
- Improve health equity in access to timely molecular testing in CRC and other tumour types by addressing disparities for patients marginalized due to age, race, geography, income or other factors.
- Implementation of value-based point of care molecular testing in the community setting to improve quality of care for patients.
- QI projects that address biomarker testing with endpoints including, but not limited to:
    - Clinical effectiveness/utility
    - Analytical validity
    - Cost-effectiveness
    - System level efficiencies
    - Social determinants

#It is not the intent of this RFP to support clinical research projects. Projects evaluating the efficacy of therapeutic or diagnostic agents will not be considered.

Budget

- Individual projects requesting up to a maximum of $100,000 (CAD) will be considered.
- The total available budget related to this RFP is $300,000 (CAD).

Project evaluation: Expert Review Panel (ERP)

The ERP will be comprised of medical experts, patient advocates, health economics and molecular pathology experts in Canada. The amount of the grant Pfizer will fund for any project will depend upon the ERP's evaluation of the proposal and costs involved and will be stated clearly in the approval notification. The ERP will evaluate the applicants for a community pathology preceptorship and will invite the successful recipient(s) directly.

Key Dates

- RFP Release Date: 28 March 2023
- Proposal Due Date: ~~31 May 2023~~
  (Application submission deadline extended: 14 June 2023)
    - Please note the deadline is 23:59 Eastern Time, i.e., New York, GMT – 5.
- Review of proposals by review panel: June – July 2023
- Anticipated award notification date: ~~31 July 2023~~ **14 August 2023**

- Grants will be distributed following a fully executed agreement and submission of final protocol, documentation of IRB/IEC approval, regulatory approval (if applicable), exemption or waiver.

Agreements

Review and Approval Process

- This grant program RFP uses an ERP to make final grant decisions.
- The panel is comprised and/ or will consult with professionals from the medical community with advanced degrees and expertise in particular clinical areas, or specific needs of a geographic region/learner group, or expertise in research, continuing professional development or quality improvement.

Application Process

How to Submit:
Note: Please read this section carefully since applications submitted not following these instructions will not be accepted and will be cancelled

- Please go to http://www.cybergrants.com/pfizer/QI and sign in. First-time users should click "Create your password". *[Note: there are individual portals for each grant application type. Please be sure to use the URL above.]*
- Click the "Start a New Quality Improvement Application" option.
- In the application:
  - For the question "Competitive Grant?" select Yes
  - Select the following Competitive Grant Program Name: **2023 Oncology Precision Medicine QI**
  - Select the following Primary Area of Interest: CRC and other tumour types
- Requirements for submission:
  - Complete all required sections of the online application and upload your project proposal (see **Appendix**) in the Full Proposal 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.

Questions:

- If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Jennifer Schreiber (jennifer.schreiber@pfizer.com), with the subject line "**2023 Oncology Precision Medicine QI in CRC**"

Grant Agreements:

- 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.

- Pfizer has drafted the terms of these agreements 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.
- Payment will only be made to requesting Institution.

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.

Appendix

Assessment of Need for the Project

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. 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 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 ensure 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 Pfizer should be aware of concerning the importance of this project, please summarize here.

Organization Detail

- 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.

Budget Detail

- The budget amount requested must be in Canadian dollars (CAD).
- While estimating your budget please keep the following items in mind:
    - General organizational running costs such as insurance, heating, lighting, rent, building maintenance may be included. Pfizer does not provide funding for capital purchases (infrastructure expenses such as equipment, purchases of software or software licenses, technology or bricks and mortar).
    - Reagents, consumables, equipment hire/leasing is acceptable and may be included in the project budget.
- 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 Pfizer 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.