



Request for Proposals (RFP)
Integration of Biomarker Testing into Treatment Planning for Metastatic
Colorectal Cancer

Association of Community Cancer Centers and
Pfizer Global Medical Grants

I. Introduction

ACCC and Pfizer Global Medical Grants (Pfizer) are collaborating to offer community cancer centers a grant opportunity for quality improvement initiatives focused on the integration of biomarker testing into treatment planning for metastatic colorectal cancer (mCRC). We are looking for community hospital-based programs and physician group practices that are interested in integrating biomarker testing into the care plan for colorectal cancer patients and utilizing the results of the genetic test to help inform disease management plans for their patients. Any ACCC member institution is eligible to apply.

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, education) to improve patient outcomes in areas of unmet medical need that are aligned with Pfizer's medical and/or scientific strategies. Projects funded by Pfizer are independent and are therefore the full responsibility of the grant requestor (and ultimately the grantee). This includes the design, implementation, sponsorship and conduct of the independent initiative supported by the grant, including compliance with any regulatory requirements. Pfizer will not be involved in any aspect of the planning or conduct of the individual projects. Pfizer only requests reports about the impact of the projects, including any measurable outcomes, in order to share them publicly.

ACCC, a not-for-profit alliance of more than 28,000 multidisciplinary practitioners and 2,100 cancer programs and practices nationwide, is dedicated to providing education and advocacy support in adapting and responding to complex changes and challenges in the delivery of quality cancer care. ACCC provides resources on operations and management for programs and practices, reimbursement issues, policy and regulatory changes at the state and national levels, trends in cancer care, integrating new technologies and therapies, and more.

This Request for Proposals (RFP) is being issued by both organizations. ACCC is the lead organization for review and evaluation of applications. A review committee, led by ACCC, will make decisions on which proposals will receive funding. Grant funding will be provided by Pfizer Inc. Collectively, \$1.5 million is available to fund between approximately 10 to 15 projects.

II. Background

Colorectal cancer (CRC) is the second leading cause of cancer death in the United States. There have been significant improvements in cancer prevention, screening, and treatment modalities for CRC resulting in a more than 50% decrease in the mortality rates. However, with the increasing number of therapies for CRC and the updated recommendations for biomarker and genomic tests in these patients, community clinicians are challenged to keep abreast of the latest clinical developments and make evidence-based choices for their patients.

According to the National Cancer Institute, about 80% of cancer patients in the US are treated by community oncologists. Community oncologists treat multiple types of cancers and see a large volume of patients. Participants from previous Association of Community Cancer Centers (ACCC) educational programs indicated that the overwhelming amount of clinical information available for cancer therapies resulted in a significant knowledge and competency gap and reiterated the need for additional education on new classes of drugs, updated clinical practice guidelines, biomarker testing, quality improvement strategies, and optimizing healthcare delivery.

Current Trends in Biomarker Testing for CRC:

Over the past years, therapeutic strategies for patients with mCRC have evolved through the development of pertinent biomarker testing and associated therapies. Biomarkers such as microsatellite instability (MSI), *RAS* and *BRAF* mutations, and *HER2* amplification have come to represent tools for oncology care providers for disease management approaches. Routine implementation, however, of guideline-concordant biomarker testing for patients with mCRC has proven challenging for several reasons.

In a recent survey of community oncology practitioners conducted by ACCC to assess the status of biomarker testing for patients with mCRC, approximately 74% of respondents reported that more than 50% of their patients with unresectable or metastatic colorectal cancer undergo biomarker testing, with medical oncologists reported as those who most commonly initiate testing orders. Twenty-one percent of centers completing the survey reported a wait time longer than 2 weeks for testing results. As such, over 40% of respondents reported that patients with mCRC who have had biomarker testing are treated with systemic medical therapy “frequently” or “almost always” before all biomarker test results are available. Significant practice variations were identified among respondents in terms of testing protocols – 52% of respondents indicated that their cancer program has no standard protocol for biomarker testing, 34% indicated that they do have a standard protocol, and 14% were unsure.

To review the full report on the ACCC survey results, please visit <http://accc-cancer.org/colorectal-survey-summary>.

III. Scope

ACCC and Pfizer encourage proposals for quality improvement initiatives focused on improving or facilitating the integration of biomarker testing into treatment planning for patients with mCRC. Proposals that directly measure process improvement will be prioritized. The sustainability and broad applicability of the approach will be important considerations when evaluating projects.

Quality improvement projects can use any accepted methodology such as PDSA (Plan Do Study Act) cycles, root cause analysis, and other data-driven approaches. They may be pilot projects or build on already existing pilot projects. It is expected that projects will be evidence-based and the proposed research/evaluation will follow generally accepted scientific principles.

Multi-disciplinary collaborations are encouraged, when appropriate, but all partners must have a relevant role. Although educational efforts for grantees and patients may be entirely appropriate components in responses to this RFP, educational objectives should be secondary to the quality improvement objectives of the proposed project and should include a quantitative endpoint or outcome measure to demonstrate an improvement in patient care.

During review, the intended outcome of the project is given careful consideration and, if appropriate based on the project goal, projects with the maximum likelihood to directly impact patient care, e.g., system-based changes, will be given high priority.

ACCC will gather the outcomes data across all the projects with a goal of disseminating the results from the quality improvement projects to a larger audience. In order to gather consistent metrics across all projects, following notification of grant support, individual grantees will be contacted by ACCC to provide guidance on data collection for their project. Grantees will be required to capture and report these data back to ACCC at the end of the project. ACCC will have regular touch points with the individual grantees to monitor the progress of the projects.

The intent of this RFP is to encourage organizations to submit Letters of Intent (LOIs) detailing concepts and ideas for projects aimed at integrating biomarker testing into treatment planning for patients with mCRC, with the ultimate goal of improving patient outcomes.

All proposals funded must:

- Be based on evidence-based care
- Be sustainable after the award funding is complete
- Collect data and report outcomes, including improved testing rates and results utilization in mCRC
- Be flexible enough to address patient variability
- Promote administrative and system efficiency

Successful proposals will have a plan for improving the utilization of biomarker testing results in treatment planning for patients with mCRC. Grant funding may not be used for testing or treatment costs.

Specific Areas of Interest:

- Quality of care assessments around guideline-concordant use of biomarker testing
 - Molecular tumor boards, tissue optimization practices, etc.
- Development of standard workflows for biomarker testing
- Standard assessment of patients for clinical trial eligibility
- Multidisciplinary care planning
- Targeted education for providers and/or patients, within the construct of a measurable QI initiative
- Addressing system-oriented issues that impact resource utilization (testing turn-around time, quality of in-house testing, adequate staffing)
- Mitigating equity and access barriers to biomarker testing for underserved patient populations
- Other areas may be considered if system-wide deficiencies in biomarker testing process are documented

IV. Letters of Intent/Proposals

This RFP model employs a 2-stage process: Stage 1 is the submission of the LOI via the online application. If an LOI is selected, the applicant will be invited to Stage 2 to submit a full program proposal. Successful applicants will be able to describe the specific clinical practice gaps that exist for their own providers, health care system, or patient community and describe what they will do to close these gaps or problems. Site-specific obstacles to success should be identified and coupled with strategies to overcome the obstacles.

Programs must describe how the intervention, when implemented, will directly affect patient care and provide evidence of sustainability (e.g., integration with an electronic medical record system), scalability (e.g., plan for dissemination/applicability beyond the proposed institution), and feasibility to be completed within the timeframe specified.

Researchers seeking funding for clinical research projects will not be considered under this RFP.

The ACCC Planning Committee has been formed to oversee this process and will utilize a formalized review procedure to accept LOIs and subsequently select the proposals of highest scientific merit. The ACCC Planning Committee has overseen the development of the RFP and will perform the peer review of applications.

The members of the ACCC Planning Committee are as follows:

Al B Benson III, MD
Professor of Medicine
Associate Director for Clinical Investigations
Robert H Lurie Comprehensive Cancer Center of
Northwestern University
Chicago, IL

Stacey A. Cohen, MD
Seattle Cancer Care Alliance/UW Medicine
Associate Professor, Division of Medical Oncology
University of Washington School of Medicine
Associate Professor, Clinical Research Division
Fred Hutchinson Cancer Research Center

Bridget O'Brien Fagan, DNP, APN, FNP-BC, AOCNP
Assistant Professor, College of Nursing
Rush University
Chicago, IL

John Kelton, PharmD
Medical Director I - Biosimilars, Biomarkers USA Oncology Medical
Pfizer Oncology

Philip Agop Philip, MD, PhD, FRCP
Kathryn Cramer Endowed Chair in Cancer Research
Professor of Oncology and Pharmacology
Leader, GI and Neuroendocrine Oncology

Vice President of Medical Affairs
Karmanos Cancer Institute
Wayne State University
Detroit, MI

Antonia R. Sepulveda, MD, PhD
Chair, Department of Pathology
George Washington University School of Medicine and Health Sciences
Washington, DC

Randolph M. Steinhagen, MD
Chief, Division of Colon and Rectal Surgery
Professor, Department of Surgery,
Icahn School of Medicine at Mount Sinai
New York, NY

V. Requirements

Clinical Area:	Colorectal Cancer
Target Audience:	Members of the health care team and administrators involved in the care of adult patients with metastatic colorectal cancer
Applicant Eligibility Criteria:	ACCC member community hospital-based programs and large physician group practices
Expected Approximate Monetary Range of Grant Applications:	<p>Individual projects requesting up to \$150,000 will be considered. The total available budget related to this RFP is \$1,500,000.</p> <p>The amount of the grant Pfizer will be prepared to fund for any project will depend upon the PRPC's evaluation of the proposal and costs involved. The approval amount will be stated clearly in the approval notification.</p> <p>The grant amounts requested must be proportional to the impact of the grant. For example, costs would be expected to be higher for multiple-site versus single-site projects. Smaller, lower-cost projects are strongly encouraged.</p>
Key Dates:	<p>Date RFP Issued: Wednesday, March 24, 2021</p> <p>LOI Deadline: Wednesday, May 12, 2021 Please note the deadline is 23:59 Eastern Time (New York, GMT-5).</p> <p>LOI Notification Date: Tuesday, July 6, 2021</p> <p>Full Proposal Deadline: Monday, August 23, 2021*</p> <p>*Only accepted LOIs will be invited to submit full proposals Please note the deadline is 23:59 Eastern Time (New York, GMT-5).</p> <p>Full Proposal Notification Date: Thursday, October 7, 2021</p> <p>Grants distributed following execution of fully signed Letter of Agreement</p>

	Project Start and End Dates: December 2021 – December 2023 (2-year project maximum; projects may be shorter)
How to Submit:	<p>Please go to www.cybergrants.com/pfizer/loi and sign in. First-time users should click “REGISTER NOW”.</p> <p>Select the following Competitive Grant Program Name: “2021 Oncology L: Biomarker Testing in mCRC”</p> <p>Requirements for submission: Complete all required sections of the online application and upload the completed LOI template (see Appendix).</p> <p>If you encounter any technical difficulties with the website, please click the “Need Support?” link at the bottom of the page.</p> <p>IMPORTANT: Be advised applications submitted through the wrong application type and/or submitted after the due date will not be reviewed by the committee.</p> <p>Questions: If you have questions regarding this RFP, please direct them in writing to the Pfizer Grant Officer, Jennifer Schreiber (jennifer.schreiber@pfizer.com) or to the ACCC at resources@accc-cancer.org, with the subject line “RFP: Biomarker Testing in mCRC”</p>
Mechanism by which Applicants will be Notified:	<p>All applicants will be notified via email by the anticipated dates noted above.</p> <p>Applicants may be asked for additional clarification or to make a summary presentation during the review period.</p>

VI. Terms and Conditions

1. This RFP does not commit Pfizer or its partners to award a grant or a grant of any size if one is awarded, nor to pay any costs incurred in the preparation of a response to this request.
2. Pfizer reserves the right to accept or reject any or all applications received as a result of this request or to cancel this RFP in part or in its entirety, if it determines it is in the best interest of Pfizer to do so.
3. For compliance reasons and in fairness to all applicants, all communications about the RFP must come exclusively to Pfizer at the email address GlobalMedicalGrants@Pfizer.com. Applicants should not contact other departments within Pfizer regarding this RFP. Failure to comply will disqualify applicants.
4. 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.

VII. Appendix: Letter of Intent Submission Guidance

The Letter of Intent (LOI) will be accepted via the online application. When answering the LOI questions in the application please keep the following in mind:

A. Title

B. Project Classification

1. There are multiple project types that are eligible for funding through this RFP. Please indicate which of the following best represents your project. More information on these classifications can be found in the Project Classification [Decision Matrix](#).

- Quality Improvement – **Preferred for this RFP**
- Education or Educational research

2. Background Information

- Quality improvement projects should be described in terms of generally accepted principles of improvement science such as those described by the IHI model for improvement or LEAN.
 - At the time of approval of a full proposal, applicants will be required to sign a letter of agreement.

C. Goal and Objectives

1. Briefly state the overall goal of the project. Also, describe how this goal aligns with the focus of the RFP and the goals of the applicant organization(s).
2. 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.

D. Assessment of Need for the Project and Preliminary Data

1. 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 these data were 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. Only include information that impacts your specific project, linking regional or local needs to those identified on the national basis, if appropriate.

E. Target Audience

1. 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.

F. Project Design and Methods

1. Describe the planned project and the way it addresses the established need
2. If your methods include educational activities, please describe succinctly the topic(s) and format of those activities.

G. Innovation

1. Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed.
2. 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.

H. Evaluation and Outcomes

1. 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.
2. Quantify the amount of change expected from this project in terms of your target audience.
3. Describe how the project outcomes will be broadly disseminated.

I. Anticipated Project Timeline - Projects must complete in two years

J. Requested Budget

1. A total amount requested is the only information needed for the LOI stage. Full Budget is not required. This amount can be adjusted at the Full Proposal stage as applicable.
2. The budget amount requested must be in U.S. dollars (USD).
3. 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.
 - Pfizer does not provide funding for capital equipment.
 - May not underwrite the entire cost of an electronic health record.
 - May not include costs of buying already developed software or clinical care pathways.
 - 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.

K. Additional Information

If there is any additional information you feel Pfizer or ACCC should be aware of concerning the importance of this project, please summarize it in within the page limitations.

Organizational Detail (not to exceed 1 page)

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 will be required at the Full Proposal stage only and should not be included with the LOI.

Please note that any project partners listed in this section should also be listed within the online system. Tax-IDs of partner organizations will be requested at the Full Proposal stage. If a partnership is only proposed, please indicate the nature of the relationship in the Organizational Detail section of your LOI.

References

1. Siegel RL, Miller KD, Jemal A. Cancer statistics, 2019. CA Cancer J Clin. 2019; 69: 7-34. Available at <https://www.ncbi.nlm.nih.gov/30620402>.
2. NCCN clinical practice guidelines in oncology (NCCN Guidelines®) – Colon Cancer. Version 2.2021- Jan 21, 2021. Accessed on February 17th, 2021.
3. Cohen R, Pudlarz T, Delattrealt J-F, et al. Molecular Targets for the Treatment of Metastatic Colorectal Cancer. Cancers. 2020; 12(9): 2350. doi: 10.3390/cancers12092350
4. Sepulveda AR, Hamilton SR, Allegra CJ, et al. Molecular biomarkers for the evaluation of colorectal cancer: Guideline summary from the American Society for Clinical Pathology, College of American Pathologists, Association for Molecular Pathology, and American Society of Clinical Oncology. J Clin. Oncol. 13; 333-37