

Pfizer Medical Education Group

Request for Proposals (RFP) – Non-Small Cell Lung Cancer (NSCLC)

Release Date: Tuesday, July 10, 2012

I. Background

“Lung cancer is the leading cause of cancer-related mortality, accounting for ~1.4 million deaths/yr worldwide (WHO, 2007) and ~160,000 deaths/yr in the United States, which is ~25-30% of all U.S. cancer deaths and more than the next three cancers (colon, prostate, breast) combined (ACS, 2009). Fortunately, the past decade has seen major advances in our understanding of the pathogenesis and management of lung adenocarcinoma in particular. Specifically, the discovery of the biologic and therapeutic importance of acquired genetic alterations in two genes that encode pharmacologically targetable tyrosine kinases involved in growth factor receptor signaling, EGFR and ALK, has changed the way these cancers are diagnosed and treated.”

This is an excerpt from the College of American Pathologists (CAP)/International Association for the Study of Lung Cancer (IASLC)/Association for Molecular Pathology (AMP) 2011 Lung Cancer Biomarkers Guideline Draft Recommendations which have been circulated for public comment and are expected to be published by all three organizations later this year. Evidence-based practice guidelines for NSCLC are also available from the American College of Chest Physicians (ACCP), the American Society of Clinical Oncology (ASCO), and most recently updated in April 2012 - the National Comprehensive Cancer Network (NCCN). Molecular testing to inform treatment has become standard practice in breast cancer, and current evidence indicates that it should also be standard practice in lung cancer.

Molecular testing in patients with NSCLC is the area of focus of this RFP.

This rapidly advancing area of science and medicine has created the need for programs and projects that help change and improve the current systems of care for NSCLC patients, including continuing education for healthcare professionals, to ensure that patients receive the highest standard of care.

II. Clinical Area Description

For patients with NSCLC, the goal is to improve clinical outcomes. There are patients with advanced-stage NSCLC who are candidates for molecularly targeted agents that are dictated by the presence of specific molecular alterations. The problem or gap in care that this RFP intends to address is that tumors are not routinely being assessed for these alterations that would guide therapy.

Molecular testing is the standard of care and it is not being followed at many cancer centers. In order for molecular testing to be optimally performed, several members of the care team are involved. Gaps or issues may occur at several steps from tissue acquisition, to tissue processing, to testing, to treatment. Cross-disciplinary and team-based solutions are needed to overcome these potential obstacles. The professional and system gaps include the tumor board team and the need for collaborative communication, the proper evaluation and work-up of patients with regard to patient navigation and appropriate tumor staging, compliance with accepted guidelines from ACCP, NCCN, and others and the proper approach to specimen acquisition, assessment and testing.

As part of the preparation for this RFP, the medical experts on the External Review Panel identified the following needed competencies or abilities of the care team members. This is a partial list and is included to provide examples only.

The medical oncologist must be able to:

1. Order biomarker testing in an efficient manner.
2. Have adequate tissue at diagnosis to enable testing.
3. Have access to appropriate treatments at approval.
4. Help team physicians understand treatment landscape and potential clinical outcomes.
5. Apply current guidelines on recommended work-up and treatment options.

The pathologist must be able to:

1. Diagnose accurately with important prognostic/treatment parameters.
2. Collaborate with surgeons/pulmonologists/interventional radiologists to optimize tissue acquisition, viability, and testing
3. Channel procedures to optimize testing results
4. Communicate with team physicians – pathologic findings, implications, and limitations
5. Understand and appreciate team physician needs and strategies.

The surgeon must be able to:

1. See themselves as a member of a team and within a continuum of disease stages so that they can understand how their actions can impact the success of the team and the whole cohort of patients, not just early stage cancer patients undergoing resection.
2. Be willing to play a role in tissue acquisition, not only in resection, diagnosis and staging.

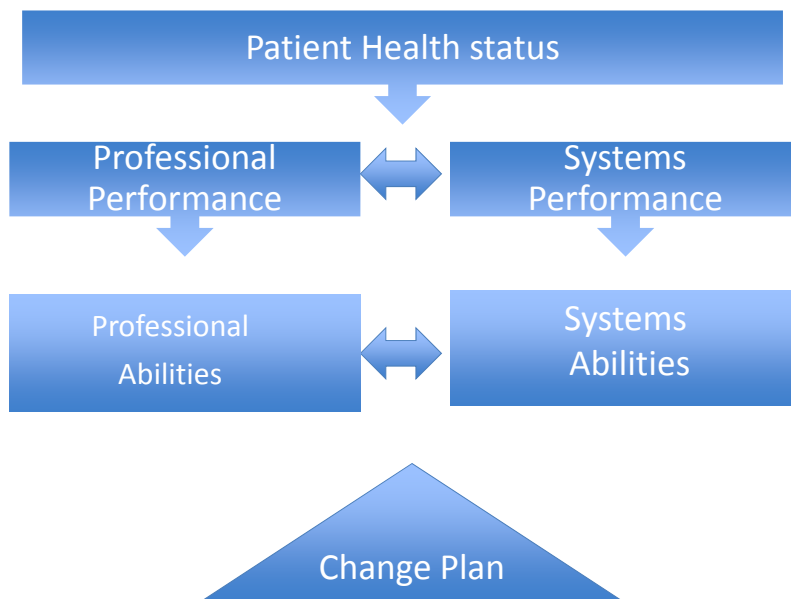
The pulmonologist or interventional radiologist must be able to:

1. Routinely acquire and process tissue specimens that are suitable for molecular testing and histological subtyping. Specimens include lymph node biopsy to TBNA, nodule biopsy to bronchoscopy or TTNA.
2. Guide team including cytopathologist.

III. Types of Proposals Requested

The goal of this RFP is to support strategic initiatives or “change plans” designed to improve the competence and performance of oncologists, pathologists, thoracic surgeons, pulmonologists, interventional radiologists and other relevant healthcare professionals involved in the care of patients with NSCLC.

In addition to focusing on individual members of the cancer care team, this RFP recognizes the role that systems factors play in the quality of patient care and how system and process gaps can potentially limit the opportunity for optimal care to be delivered. (See Figure 1). Therefore, “change plans” can and should include efforts to assess and change systems and processes that may be barriers to optimal care.



Respondents to this RFP should have assessed their system of care and have a plan for further detailed assessment. They should be able to describe the quality gaps or problems in practice that exist and describe what they will do to close these gaps or problems. A “gap” is considered to be the difference between what is currently happening and what should be happening to meet the highest optimal standard of care. Gaps may be in the role of individual contributors meaning the ability or competencies of the healthcare professionals themselves. Also, the gaps may be in the abilities of the systems in which they work to promote or allow proper treatment, for example in unclear transitions of care, limitations in order sets, or re-imbursement issues.

Assessment should include a plan for identifying appropriate measures and metrics in order to understand the current care, to measure results, and know whether or not the project or

intervention has worked. Measures and metrics may be used at multiple stages of an initiative. For example, an education component of an initiative may be assessed by determining whether the knowledge of participants increased, but the overall initiative may ultimately be measured in terms of impact to patient care. For example, one performance measure that exists in the U.K. (www.nice.org.uk) is

People with lung cancer have adequate tissue samples taken in a suitable form to provide a complete pathological diagnosis including tumour typing and sub-typing and analysis of predictive markers.

An applicant may choose to use a measure similar to this one, or may identify and define their own measures and metrics that are most applicable to their own care setting, and to their own planned project. All projects must include verifiable outcomes metrics or verifiable data that shows improved multi-disciplinary application of current guidelines.

IV. Requirements

Geographic Scope:	United States is primary area of focus. Proposals related to other countries and global efforts may be considered but are not the priority for this RFP.
Applicant Eligibility Criteria:	Cancer care centers; hospitals and clinics; medical, nursing, allied health, or pharmacy professional schools; healthcare institutions, networks and systems; professional associations, member societies and other not-for-profit entities.
Grant Request Amounts:	Individual grant requests up to a maximum of \$1,000,000 will be considered, however smaller projects (in the approximate range of \$100K to \$300K) are preferred. The total available budget related to this RFP is \$2,000,000, including indirect costs. The maximum allowed overhead rate is 28%, and the maximum dollar amount delineated above includes overhead costs.

<p>Key Dates:</p>	<p>Letter of Intent (LOI) due date: 08/09/2012</p> <p>Anticipated LOI Notification Date for submission of full proposal: 09/14/2012</p> <p>Please note, full proposals can only be submitted following acceptance of an LOI.</p> <p>Full Proposal Deadline: 10/18/2012</p> <p>Anticipated Full Proposal Notification Date: 11/16/2012</p> <p>Grants awarded following execution of fully signed Letter of Agreement (LOA)</p> <p>Period of Performance: 12/2012 to 12/2014</p>
<p>How to Submit:</p>	<p>Submit LOIs online via the Pfizer Medical Education Group website www.pfizermededgrants.com</p> <p>Submit LOIs in the clinical area: LOI-RFP Lung Cancer</p> <p>Requirements for submission: Organizations must first register on the Pfizer website. Please allow 2-3 business days to complete the registration process in advance of the LOI submission deadline. Complete all applicable sections of the online application and upload the Letter of Intent. See details on LOI Guidance below.</p>
<p>Questions:</p>	<p>Please submit questions in writing. Send questions to MedEdGrants@Pfizer.com with the subject line "RFP Lung Cancer" Responses to common questions will be posted on the PFE MEG RFP Web site www.Pfizermededgrants.com.</p> <p>Other communications may also be directed to the MEG Education Director for this clinical area, Jackie Mayhew, via email (jacqueline.mayhew@pfizer.com)</p> <p>For any general, system or process-related questions, please contact the Grant Manager, Laura Bartolomeo, via email (laura.bartolomeo@pfizer.com).</p> <p>The Pfizer Medical Education Group can be contacted through e-mail (mededgrants@pfizer.com) or voicemail (1-866-MEG 4647).</p>

V. Terms and Conditions

1. Complete TERMS AND CONDITIONS for Certified and/or Independent Professional Healthcare Educational Activities are available upon submission of a grant application on the Medical Education Group website www.Pfizermededgrants.com.
2. This RFP does not commit Pfizer to award a grant, or to pay any costs incurred in the preparation of a response to this request.
3. Pfizer reserves the right to announce the details of successful grant application(s) by whatever means insures transparency, such as on the Pfizer website, in presentations, and/or in other public media.

VI. Letter of Intent Submission Guidance

The Letter of Intent (LOI) is intended to be a brief concept document, describing the proposed project at a high level. The External Review Panel will select LOIs that best align with the intent of the Request for Proposal. All applicants will be notified with either an acceptance or a declination. Successful applicants will be asked to submit a full grant proposal for consideration for funding.

LOIs must be single spaced using Calibri 12-point font and 1-inch margins. There is a 3-page limit.

Please include the following information in the LOI:

- A. Project Title
- B. List of the organization(s), department(s), or team members involved in project, as well as principal investigator.
- C. Primary goal(s) and brief description of project
- D. Baseline data summary, initial metrics or project starting point. What is the practice gap that will be addressed or improved?
- E. Technical Approach. What educational or quality improvement methods will be used as part of the project?
- F. Describe how this initiative builds upon existing work, pilot projects, prior collaborations, or ongoing programs.
- G. Explain how the impact of the project would be evaluated. What are the goals or target measures of success? How might the program/project be sustained after the funding expires? To what extent is the program/project disseminable?
- H. Project Timeline
- I. Requested Amount
- J. CV of PI (does not count toward 3-page limit)

Please note that the three (3) page limit for the Letter of Intent (LOI is inclusive of additional information of any kind. A submission of any more than three (3) pages WILL BE REJECTED and RETURNED UNREVIEWED. The CV of the PI should be the only additional documentation beyond the three (3) page LOI.

VII. Full Proposal Grant Review and Decision Making Criteria

In order to provide some guidance for applicants considering submission of a LOI, some of the criteria that will ultimately be used to evaluate full grant proposals will be:

- The clarity and convincing nature of the “needs and gaps” analysis of the current practice and the metrics by which the applicant will assess their success and achievement of their goals and objectives.
- The assessment of current practice including aggregate patient level data, including a description of what quality indicators or performance measures will be utilized to measure the impact of the initiative proposed, and the rationale of why these were chosen.
- The assessment of barriers and possible solutions, including an approach for addressing unexpected contingencies.
- The inclusion of integrated, comprehensive approaches to change that addresses not only performance gaps of individual healthcare providers but also the performance of the entire team and the healthcare delivery system.
- The extent of intra-organization and/or inter-organization collaboration.
- The extent to which tools, resources, educational materials, or courses will be open-source and available for others to use following the completion of proposed initiative.
- Evidence of sustainability and/or exportability and the degree to which the proposal provides a model that could be disseminated or replicated.

Successful LOI applicants will be asked to include in their full proposals: biographical sketches of project team members; and also to the extent possible flow charts of specimen flow and patient flow.

VIII. External Review Panel Members

This RFP was developed with the assistance and input of an External Review Panel, consisting of six experts in education or in the care of patients with lung cancer and one Pfizer employee. Letters of Intent and full Grant Proposals will be reviewed and decided upon by the External Review Panel. Maureen Doyle-Scharff, MBA, PhD (ABD) Sr. Director, Team Leader of the Pfizer Medical Education Group serves as ex-officio secretariat for the panel. External Review Panel members for this RFP are listed below.

Robert L. Addleton, Ed.D., LPC, FACEHP, CCMEP
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Conflict of Interest:

Each (non-Pfizer) External Review Panel member has signed an agreement that during their tenure on this panel they shall not engage in any other work for or with Pfizer. In addition, during the term, members of one's immediate department or personnel with whom the member works regularly shall be ineligible to submit Letters of Intent in response to RFP(s) issued by this panel.

IX. Acknowledgement

We gratefully acknowledge Robert D. Fox, EdD for his guidance throughout this process and for providing the External Review Panel with a framework upon which to develop this RFP.