Educational Grant Request in Support of the

2013 Tumor Board Curriculum: Molecular Testing in Non-Small Cell Lung Cancer

Submitted To:

Pfizer

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Overall Aim and Objectives: Program Synopsis

Title: *2013 Tumor Board Curriculum: Molecular Testing in Non-Small Cell Lung Cancer*

Clinical Synopsis: Testing appropriate patients with advanced NSCLC for ALK rearrangements and EGFR mutations is critically important to ensure delivery of the most effective lung cancer treatment. Crizotinib is effective in treating ALK rearranged tumors and erlotinib is effective in tumors with activating mutations in EGFR, leading in recent years to dramatic responses in selected groups of patients treated with these drugs.[1-4] The NCCN Guidelines for Non-Small Cell Lung Cancer (NSCLC) currently recommend ALK rearrangement testing and EGFR mutation testing for patients with advanced nonsquamous NSCLC (see http://www.nccn.org). Using these tests to select targeted therapy has been shown to improve outcomes for the patients carrying one of these mutations.[1,4,5] However, many patients with advanced nonsquamous NSCLC are not receiving molecular testing because of gaps in physician knowledge of its critical importance as well as lack of patient awareness.

Goal of Project: The goal of this project is to ensure that pathologists, medical oncologists, radiation oncologists, surgical oncologists, interventional radiologists, pulmonologists, and other relevant healthcare professionals, including nurses have the knowledge and skills necessary to order, perform, and use the information acquired from biomarker testing to optimally manage patients with advanced NSCLC.

Brief Description of Format: The 2013 Tumor Board Curriculum: Molecular Testing in NSCLC will feature several educational interventions, including:

- Integrated series of four (4) live webinars, which will later be archived for on-demand viewing on the NCCN learning management system
- Four discussion boards associated with the webinars, moderated by the live webinar speakers
- Dissemination of free subscriptions to the NCCN Biomarkers Compendium for one month to all live webinar attendees who have not previously subscribed
- Electronic slide decks attainable through NCCN's learning management system for attendees to use during tumor boards at their respective institutions
- Patient education handouts
    - Dissemination of the NCCN Patient Guideline for Lung Cancer
    - Development and dissemination of patient education materials emphasizing the importance of tissue biopsy and biomarker testing during clinical decision making.

Topic areas to be addressed through this curriculum include:

- Interdisciplinary Cooperation: A Model Tumor Board in NSCLC
- Tissue Acquisition in NSCLC: Surgical and Interventional Radiology Perspectives
- Best Practices in Molecular Testing in NSCLC
- Patient Navigation: Role in Molecular Testing in NSCLC

Project Start and End Date: Preparation of patient education handouts and electronic slide decks will begin January 1, 2013. The four live webinars will launch in May 2013, with a discussion board following each one of the webinars. Webinar attendees may access a free one-month subscription to the NCCN Biomarkers Compendium® within a sixty-day window following the webinar in which they participate. In order to further broaden the reach of these webinars, they will be archived and posted in NCCN's learning management system by August 2013. This project will conclude by August 2014.

Learning Objectives: Following this program, participants should be able to:

- Describe the respective contributions made by various multidisciplinary teams to the management of NSCLC
- Discuss the molecular testing considerations for patients with ALK rearrangements and EGFR mutations
- Discuss the considerations and challenges of obtaining appropriate tissue samples
- Develop core communication messages for use with patients in advance of testing decision making

Target Audience: This educational program is designed to meet the educational needs of physicians, nurses, pharmacists, and other healthcare professionals who manage patients with cancer. The physician target audience will include a wide variety of physicians involved in the diagnosis and treatment of NSCLC patients including pathologists, medical oncologists, radiation oncologists, surgical oncologists, interventional radiologists, and pulmonologists. The program will also meet the educational needs of NSCLC patient navigators. While not our primary audience, patients are an indirect target audience for this educational initiative.

Anticipated Attendance/Readership: NCCN anticipates a total of 100 learners per combined webinar / discussion board and archived webinar, for a total of 800 learners.

CE Certification: This activity will be certified to offer approximately eight (8) credits (four for the live webinars and four for the archived webinars). NCCN is accredited by the Accreditation Council for Continuing Medical Education to provide continuing education for physicians, by the American Nurses Credential Center to provide continuing education for nurses, and by the Accreditation Council for Pharmacy Education to provide continuing education for pharmacists.

Educational Outcomes Measurement: The proposed educational activity will result in Level 5 outcomes, according to Moore's 2009 expanded outcome framework. Level 5 is defined by Moore as the degree to which participants do what the CME activity intended them to be able to do. To measure the effectiveness of this activity, NCCN's outcome measurement will collect self-reported data on clinician application of content from the educational activity to practice and change in practice.

NCCN will collect data through various instruments: the pre-activity survey, the activity evaluation, an immediate post-test, a 30-day post-test, and a post-activity follow-up survey. The pre-activity survey will measure baseline practice. The evaluation and follow-up survey will ask learners, at

different time intervals, what they are doing in their practice at that later point in time. Analysis of this information will determine whether a practice change/performance improvement has occurred.

The target measures for success will be individual comparisons of pre-program practice and post-program practice. Increases or improvements in self-reported performance will measure success. The value of the program will be extended through electronic slide decks in NCCN's learning management for attendees' use.

Technical Approach: Needs Assessment

Most patients with lung cancer are diagnosed with advanced non-small cell lung cancer (NSCLC). Currently, 5-year survival is only about 16% for patients with all stages of lung cancer and a dismal 4% for patients with metastatic disease.[1] However, recent data have shown that molecular testing can be used to select more effective treatment for patients with advanced disease and thus improve outcomes.[2-4] Using molecular tests to select targeted therapy has been shown to improve outcomes for patients carrying anaplastic lymphoma kinase (ALK) rearrangements and epidermal growth factor receptor (EGFR) mutations.[5-7] Crizotinib is effective in treating ALK rearranged tumors, and erlotinib is effective in tumors with activating mutations in EGFR, leading in recent years to dramatic responses in selected groups of patients treated with these drugs.[5,6,8,9] Crizotinib and erlotinib are oral tyrosine kinase inhibitors.[4]

Testing appropriate patients with advanced NSCLC for ALK rearrangements (also known as ALK gene fusions) or EGFR mutations is critically important to ensure delivery of the most effective lung cancer treatment.[4,10,11] Symptoms dramatically improve in patients with advanced nonsquamous NSCLC who receive either crizotinib or erlotinib, the oral therapy is easy to administer and tolerate, and severe side effects are rare.[2,8] Patients often quickly respond to crizotinib and have prolonged progression-free survival.[6,9] Currently, crizotinib and erlotinib are the only treatment options for patients with ALK rearrangements and EGFR mutations in the United States. Clinical utility is a risk/benefit assessment that can be used to determine whether molecular testing should be adopted. Molecular testing for ALK rearrangements and EGFR mutations has clinical utility because the benefits of testing exceed the risks.[3,12,13] The NCCN Guidelines for NSCLC currently recommend testing for ALK rearrangements and EGFR mutations in patients with advanced nonsquamous NSCLC (www.nccn.org).[3] However, many patients are not being offered molecular testing because of gaps in the management and education of patients with advanced nonsquamous NSCLC.

The NCCN proposes a series of webinars specifically developed to educate physicians involved in the diagnosis and treatment of NSCLC patients including pathologists, medical oncologists, radiation oncologists, surgical oncologists, interventional radiologists, and pulmonologists, as well as patient navigators about the value of molecular testing in advanced nonsquamous NSCLC.[14] Gaps in awareness of the need for molecular testing and in the practical considerations of implementing and interpreting testing can be addressed by this educational program. Identified practice gaps include insufficient or inappropriate tissue samples (for example, necrotic samples), excessive turnaround times for testing, and inefficient use of tissue for testing, which decreases the amount available for molecular assessment.[4,15] Although multidisciplinary cooperation is key to the global treatment of these patients, some issues are of primary concern to one group of clinicians or another. The webinars will include a mock tumor board to illustrate the multidisciplinary cooperation required to optimally manage NSCLC patients and will be targeted to a multidisciplinary audience. Another webinar will address tissue acquisition with surgeons and interventional radiologists being the primary audience. A third will address biomarker test selection and validation with pathologists being the primary audience. A fourth will focus on patient education needs with patient navigators and oncology nurses being the primary audience. Major practice gaps will be identified in each of these programs and solutions to remedy the gaps

based on experience at comprehensive cancer centers (that is, NCCN Member Institutions) will be presented.

Role and Information Needs of the Pathologist Assessing Non-Small Cell Lung Cancers

Pathologists are an integral part of the multidisciplinary process of managing patients with NSCLC. As the use of biomarkers in lung cancer has become more sophisticated, the role of the pathologist has become pivotal in clinical decision making for this disease. Actionable molecular assays are now available which may guide treatment decisions for NSCLC.[3] The pathologist needs to know which biomarkers have clinical utility. Also, the pathologist must know which tests and test kits are reliable, which assays can be done in house, and which can be sent to a central laboratory. Issues of analytic validity and clinical validity are also important to the selection, use, and evaluation of novel biomarker tests as they become available.

In NSCLC management, biomarkers supplement traditional histologic classification and staging studies to refine diagnosis and treatment paradigms. Three markers have actionable clinical relevance in management of this disease: EGFR mutations, KRAS mutations, and ALK rearrangements. Several methods are available for testing for EGFR mutations.[21] The current NCCN Guideline for NSCLC does not recommend a particular method, noting only that mutation testing is preferable to either 1) FISH assessment of EGFR copy number, or 2) immunohistochemistry to assess EGFR protein levels (http://www.nccn.org).[22-24] Several studies analyzing both EGFR and KRAS mutations have shown that the two mutations are present in mutually exclusive populations.[25-27] FISH and immunohistochemistry have both been used to detect ALK rearrangements, and some clinicians suggest confirming mutation status using both assays.[10,20] However, testing for ALK rearrangements by FISH is the only FDA-approved ALK test available at this time. Detailed guidelines for EGFR and ALK testing in lung cancer are in progress, which are a collaborative effort among CAP (College of American Pathologists), AMP (Association for Molecular Pathology), and IASLC (International Association for the Study of Lung Cancer).[15] These guidelines should be a valuable resource for guideline developers and practitioners. A number of additional somatic mutations are detected in lung cancer, and molecular tests for them may enter clinical practice for NSCLC in the near future. These include mutations in BRAF, HER2 (ERBB2), AKT1, MAP2K1 (MEK1), and PIK3CA; gene amplifications in MET; or fusions involving the ROS tyrosine kinase. Each of these is present in a small percentage of lung cancer patients (1%-5%) and will require further validation before general use to direct treatment.[28]

Pathologists face a number of issues when incorporating biomarker testing into their work flow. Some of the challenges to clinical adoption include assay variability and inadequate analytic validation, poor study design and analysis, and inadequate reporting,[29-35] as well as practical obstacles (such as lack of resources, personnel, or expertise in smaller clinical laboratories). In addition, the pathologist needs to work closely with the surgeon or the interventional radiologist to ensure that adequate tissue is available to perform the assays. Since identification of biomarkers is most relevant in the metastatic setting, obtaining sufficient biopsy material to perform a series of tests can be challenging. Pathologists must make decisions about which tests should have priority based on likelihood of an actionable result.

In addition, an increasing number of multi-analyte tumor markers require comprehensive technologies and computational algorithms but hold promise in situations like metastatic NSCLC where limited tissue is available for analysis. However, these platforms and analytic approaches may only be available at major cancer centers and represent challenges to independent validation and verification.

The pathologist must also understand the concepts of analytic and clinical validation which are used to identify the specific tests that are most reliable and informative.

Analytic Validation. Analytic validation focuses on determining how accurately and reliably the assay measures the molecular event of interest.[33,35,36] Even assays that are routinely performed in the laboratory require analytic validation within a clinical laboratory setting in order to be used to make clinical decisions. Results can be influenced by various factors, both within and outside of the control of the pathology laboratory. Clinical laboratories should understand the effect that pre-analytic variables and specimen processing have on assay performance so as to ensure reproducible findings.

Clinical Validation. Clinical validation assesses the strength of association between the assay results and the clinical outcome of interest; be it diagnostic, prognostic, or predictive. Many measures are used to assess these associations. These analyses assess questions such as; if the test is positive, can we be sure that the clinical state is positive (positive predictive power)? If the test is negative, can we be sure that the clinical state is negative (negative predictive power)?

Role and Information Needs of Non-Pathologist Physicians Involved in the Diagnosis and Treatment of NSCLC Patients

A wide variety of clinicians need to work together to treat NSCLC patients including medical oncologists, radiation oncologists, surgical oncologists, interventional radiologists, and pulmonologists. Minimally invasive techniques to obtain biopsy samples (e.g., endobronchial ultrasound-guided transbronchial needle aspirates [EBUS-TBNA]) may be preferable for patients with advanced NSCLC who are not surgical candidates or those who require additional biopsies.[4,10,11] Studies show that ALK gene rearrangements and EGFR mutations can be detected using these small tissue samples.[10,11] Accurate determination of histology is essential for molecular testing. Although ALK rearrangements and EGFR mutations are rare, they tend to occur in patients with nonsquamous NSCLC.[10,16] In addition, ALK rearrangements and EGFR mutations are mutually exclusive.[5,17] The NCCN Guidelines for NSCLC recommend that patients with adenocarcinoma or large cell carcinoma histology (that is, nonsquamous NSCLC) should have molecular testing for ALK gene rearrangements and EGFR mutations (http://www.nccn.org).[11,18]

ALK rearrangements can be detected using the FDA-approved ALK break-apart fluorescence in situ hybridization (FISH) probe test, which is considered the gold standard because it was a requirement for enrolling patients on clinical trials for crizotinib.[18] However, recent data suggest that the ALK FISH probe test may not detect all patients with ALK rearrangements.[19] Immunohistochemistry or RT-PCR may be more accurate.[18,19] One solution to this dilemma is to screen appropriate patients with nonsquamous NSCLC for possible ALK rearrangements using immunohistochemistry; positive

immunohistochemistry results can then be assessed and confirmed using the ALK break-apart FISH probe test and/or reverse transcriptase—polymerase chain reaction (RT-PCR).[10,20] Thus, molecular testing of ALK rearrangements is evolving and clinicians should be aware of the latest developments. Results of these tests are key to the selection of optimal systemic therapy for NSCLC patients by the medical oncologist.

Role and Information Needs of Patient Navigators in Non-Small Cell Lung Cancer

Oncology Patient Navigators are professional nurses or healthcare professionals who have experience working with people with cancer and understand their challenges. Patient navigators may also be called care managers, case managers, or be referred to by other titles. Navigators help remove roadblocks to treatment, so that patients are able to keep their appointments, follow their treatment regimens, and receive the support services they need. Navigator goals[37] include:

- Educating, advocating for, and helping cancer patients navigate the complex medical world throughout the entire course of cancer treatment and beyond.
- Improving patient outcomes by working to eliminate barriers to care.
- Being a central point of contact for information about cancer resources and community support services.
- Serving as the cancer patient's personal care coach.

Patient navigators may work in a variety of settings. Most work directly with patients in academic and community cancer centers or oncology practice settings. Others work in managed care organizations, where they work with patients telephonically. Navigators in most settings do not work exclusively with lung cancer patients, with those working in academic cancer centers being the most likely exception. Rather, they most often work with patients that have a variety of different types of cancer. Regardless of setting, these navigators need to keep abreast of advances in clinical knowledge and their application to individual patients. The fact that most do not focus exclusively on lung cancer makes it even more challenging to stay current on new clinical developments.

Additionally, nurses in all types of roles, including nurse navigators, are challenged to find the time and organizational support to attend clinical conferences and programs. Access to educational content that is targeted to their needs is highly valued, especially when the educational programming is convenient and affordable.

As described elsewhere in this proposal, the treatment of NSCLC now requires clinicians to know the results of molecular assays in order to provide the most effective treatment. Patient navigators need to be able to understand these requirements and be able to explain to patients why additional testing is important and why not all lung cancers are the same. Knowledge in this area is highly technical and is increasing at a rapid pace, posing a significant challenge for physicians and other healthcare professionals alike. In order to be an effective member of the patient care team, a patient navigator must keep up to date on new knowledge that has direct implications for patient education and patient care.

Information Needs of the Patients with Non-Small Cell Lung Cancer

Health information can be overwhelming. To address this challenge, NCCN uses many strategies to create user-friendly patient education handouts. The NCCN Guidelines for Patients® and handouts based on these NCCN Guidelines for Patients will provide patients with the same information that cancer professionals receive from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) in patient-friendly formats.

One of the most important strategies is the application of plain language principles. Plain language is communication that users can understand the first time they read or hear it.[41] The major principles of plain language include targeting the audience, good organization, and a clear writing style.

Inclusion of definitions is another strategy used to help readers comprehend the material. Words that readers may not know will be defined in the text or a sidebar. Words with sidebar definitions are underlined when first used on a page. The sidebar also may contain cross-references to other pages with more information and the full name of acronyms as space permits. A dictionary of all defined terms is included in the NCCN Guidelines for Patients®.

Just as important as the writing style, the graphic design of the handouts will aim to increase usability and comprehension. Clinical images will be included to help readers learn about cancer, cancer tests, and treatments. Photography is also added to enliven the handouts and hold readers interest. A typography will be chosen based on its readability. Readability is also addressed by short text lines, sufficient white space, and appropriate use of color.

Health literacy is defined as "the ability to obtain, process, and understand basic health information and services needed to make appropriate health decisions." [38] According to the National Assessment of Adult Literacy, 90% of adults have limited health literacy.[39] Low health literacy negatively affects people's ability to find and use health information. It has also been linked to poor health outcomes such as more severe illness at initial workup, poorer self-management of illness, and greater use of emergency medicine.[40]

Health literacy involves not only reading and comprehension skills but cognitive abilities to obtain, process, and respond to information. Molecular testing for NSCLC is a relatively new requirement that not all health care professionals—let alone patients—know about. The provision of patient education handouts aims to empower patients. The handouts will promptly provide patients with current information and will be designed in a patient-friendly format to increase usability and comprehension. As such, the patient education handouts can help with information exchange and shared decision-making between professionals and patients. The end result will likely be improved health outcomes, such as extended survival.

Many people lack knowledge or have misinformation about their body, diseases, and treatment. The NCCN Guidelines for Patients® address all these topics. Patients are taught the basic anatomy of the lungs and that lung cancer is a disease of cells. To understand molecular testing, biopsy tests

are described, and patients are alerted that more than one biopsy may be done to collect adequate amounts of tissue. Furthermore, explanations of genes, EGFR and ALK gene mutations, and cell receptors are given as an essential preface to explaining targeted therapy. Information on targeted therapy includes the mechanisms of drugs and the NCCN recommendations of use.

NCCN proposes to develop a stand-alone patient education piece using these principles describing the need for and mechanics of biomarker testing and its implications for treatment selection. Patient awareness of the need for molecular testing is critical for success. Patients need to understand that testing for ALK rearrangements and EGFR mutations is beneficial because targeted therapy has been shown to dramatically improve outcomes. Patients should know that crizotinib and erlotinib are very effective oral agents with low toxicity; these agents often improve symptoms and are associated with prolonged progression-free survival.

Learning Objectives

Following this program, participants should be able to:

- Describe the respective contributions made by various multidisciplinary team members to the management of NSCLC
- Discuss the molecular testing considerations for patients with ALK rearrangements and EGFR mutations
- Discuss the considerations and challenges of obtaining appropriate tissue samples
- Develop core communication messages for use with patients in advance of testing decision making

Competencies

This educational program is designed to meet the educational needs of physicians, nurses, pharmacists, and other healthcare professionals who manage patients with cancer. With respect to the physician target audience, this program will meet the educational needs of pathologists, medical oncologists, radiation oncologists, surgical oncologists, interventional radiologists, and pulmonologists. The program will also meet the educational needs of patient navigators.

2013 Tumor Board Curriculum: Molecular Testing in Non-Small Cell Lung Cancer will meet the following clinician competencies:

- IOM: Employ evidence-based practice
- ACGME/ABMS: Demonstrate medical knowledge
- ACPE: Practice evidence-based medicine; deliver patient-centered care
- ANCC: Demonstration of a learned skill and implementation of that skill in practice/healthcare setting

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Technical Approach: Intervention Design and Methods

In January 2013, NCCN plans to begin preparation of patient education handouts and electronic slide decks to be used in clinical practice. NCCN will create and disseminate electronic versions of the NCCN Patient Guidelines for Lung Cancer®. NCCN will also create and disseminate electronic patient education materials emphasizing the importance of tissue biopsy and biomarkers in clinical decision making. When an individual is given a diagnosis of cancer or experiences a change in the status of his or her disease, the various treatments and side effects can be overwhelming. Many people with cancer experience anxiety and distress because of the attitudes and fears attached to it. Educating people with cancer about their condition, their treatment options and their own role in the treatment and management of their disease can help relieve stress and help them become active participants in their care.

In May 2013, NCCN plans to launch an integrated series of four (4) live webinars on the topics of:

- Interdisciplinary cooperation: A Model Tumor Board in NSCLC
- Tissue Acquisition in NSCLC: Surgical and Interventional Radiology Perspectives
- Best Practices in Molecular Testing in NSCLC
- Patient Navigation: Role in Molecular Testing in NSCLC

NCCN plans to use a case-based approach to enhance the learning experience of the tumor board style webinars. An initial case study will be developed that evaluates patients with advanced NSCLC for ALK rearrangements and EGFR mutations for appropriate testing. Webinars will focus on the individual needs of each of the specialties involved in testing, providing specific guidance on how to ensure appropriate management. The goal of these webinars will be 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 order to extend the reach of the live webinars, NCCN will produce four (4) archived enduring materials to be hosted on NCCN's new Learning Management System, http://education.nccn.org by August 2013. Each archived webinar will be available for one year, expiring in August 2014.

Immediately following each live webinar will be a discussion board associated with the topic of the webinar, each moderated by webinar speakers. These discussion boards will allow learners to ask

questions of the expert faculty and will allow for interaction in a small group environment, which will reinforce the education and enhance learning.

NCCN plans to offer a free subscription to the NCCN Biomarkers Compendium® for one month to all live webinar attendees who have not previously subscribed. Based directly on the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), the NCCN Biomarkers Compendium® contains information designed to support decision-making about the appropriate use of biomarker testing in patients with cancer. The goal of the NCCN Biomarkers Compendium® is to identify how biomarkers are appropriately used to screen, diagnose, monitor, and provide predictive or prognostic information to ensure, ultimately, that patients and clinicians have access to appropriate testing. It is NCCN's goal that this product will aid in the distinction between clinically useful biomarkers and those that are of research interest but have not yet been proven clinically useful in standard care. NCCN expects that this compendium will eventually be used by payers in much the same way the NCCN Drugs & Biologics Compendium (NCCN Compendium®) is: to determine coverage of appropriate biomarker information based on the evaluations of NCCN panel members. By offering the free subscriptions, learners will be able to use the Biomarkers Compendium® to further their education and enhance their learning.

Finally, NCCN plans to develop electronic slide decks to be added in NCCN's learning management system for attendees to download and use during tumor boards at their respective institutions. The goal of these slide decks is to allow clinicians to further disseminate the education related to molecular testing in lung cancer to their peers and to enhance their own knowledge through group discussions at their institutions.

Rationale for Selection of Educational Formats

To determine the best possible format for educational programming, NCCN uses the following approach:

- An analysis of components of existing programs
- Our assessment of an educational need or knowledge gap
- Identification of the target learners, including their healthcare role and past and current experiences in the identified program area
- Development of learning objectives to address the educational gaps
- Identification of the most efficacious learning formats for the learner and the learning objectives
- Assessment of means of measuring the outcomes of the program.

This educational program implements a number of adult learning principles, including the following:

- The need to know the reason for learning
- Experience as the basis for learning activities
- Relevance of content
- Problem-centered nature of learning
- Self-direction, independent learning, and empowerment

Proposed Speakers

The principal investigator, Mark G. Kris, MD, of the Thoracic Oncology Service at Memorial Sloan-Kettering Cancer Center is a longtime member of the NCCN NSCLC Panel. Since multidisciplinary management is essential in treating NSCLC, additional faculty will include an interventional radiologist, a thoracic surgeon, a pathologist, a pulmonologist, and a NSCLC Patient Navigator. NCCN will seek to recruit expert faculty from NCCN Member Institutions for the activity. Final selection will be based on availability.

Technical Approach: Evaluation Design

The proposed educational activity will result in Level 5 outcomes, according to Moore's 2009 expanded outcome framework. Level 5 is defined by Moore as the degree to which participants *do what* the CME activity intended them to be able to do. To measure the effectiveness of this activity, NCCN's outcome measurement will collect self-reported data on clinician application of content from the educational activity to practice and change in practice. Thus NCCN will measure the activity for Level 5 subjective outcomes through self-report of performance.

NCCN will collect data through various instruments: the pre-activity survey, the activity evaluation, an immediate post-test, a 30-day post-test, and a post-activity follow-up survey. The pre-activity survey will measure baseline practice by asking questions during the registration process regarding use of biopsies and molecular testing in patients. The evaluation and follow-up survey will ask learners, at different time intervals, what they are doing in their practice at that later point in time. Analysis of this information will determine whether a practice change/performance improvement has occurred.

Past activity evaluations demonstrate community oncologists' self-reported intent to change their practice. The evaluations show that community oncologists who participate in NCCN educational programs intend to change their practice as a result of the education and plan to implement Guideline updates learned at the educational activity into their practice. Evaluations from past activities reveal that on average ninety-five percent (95%) of respondents plan to implement updates from the activity into their practice.

The activity evaluations assess:

- The extent to which the educational objectives are being met;
- The quality of the instructional method, faculty and content;
- Change in participant's knowledge and attitudes;
- Change in practice as a result of participation;
- Use of clinical algorithms and impact of activity; and
- How participants will apply what they learned to their practice.

The second outcomes measurement instrument will be a post-test based on the learning objectives from the activity, taken immediately following the activity. The results will determine if clinicians have experienced a change in knowledge based on the content of the activity.

The third outcomes measurement instrument will be a later post-test based on the learning objectives from the activity. Approximately 30 days after the activity, NCCN will send a link to the post-test to activity participants. The results will determine if clinicians have maintained the change in knowledge based on the content of the activity. As an additional learning enhancement, once the post-test has been closed, those who participated will receive the correct answers. This will serve as an educational resource which clinicians can reference in their practice.

NCCN recognizes that in addition to measuring change in knowledge, it is vital to measure actual change in practice. In order to determine whether participants of the activity implement their intended practice change, NCCN will send all participants of the activity a brief post-activity survey. The survey, sent 60 days after the activity, will include the following questions:

- What is your professional credential?
- Did you implement the practice change you intended to make upon completion of the educational activity?
- If yes, what changes did you make?
- If no, what were the barriers that prevented you from implementing the changes?

Past results from follow-up surveys demonstrate that clinicians have retained what they learned and indeed have made practice changes. As a result of these self-reported practice changes, NCCN is achieving Level 5 outcomes.

The target measures for success will be individual comparisons of pre-program practice and post-program practice. Increases or improvements in self-reported performance will measure success. The value of the program will be extended through electronic slide decks in NCCN's learning management for attendees' use. These data will be collected and used to determine continuing practice gaps and identify areas of educational need.

OUTCOMES REPORTING

Outcomes data will be reported to supporters through quarterly interim updates. Final outcomes will be published with the final financial reconciliation.

Technical Approach: Detailed Work Plan and Deliverables Schedule

- Preparation of electronic patient education handouts and electronic slide decks will begin January 1, 2013.
    - Dissemination of the NCCN Patient Guideline for Lung Cancer
    - Development and dissemination of patient education materials emphasizing the importance of tissue biopsy and biomarkers during clinical decision making.
- The four live webinars will launch in May 2013, with a discussion board following each one of the webinars.
    - Integrated series of four (4) live webinars, which will later be archived for on-demand viewing
    - Four discussion boards associated with the webinars, moderated by webinar speakers

- In order to broaden the reach of these webinars, they will be archived and posted in NCCN's learning management system by August 2013. Electronic slide decks will also be added in NCCN's learning management system for attendees to use during tumor boards at their respective institutions.
- This project will conclude by August 2014.

Topic areas to be addressed through this curriculum include:

- Interdisciplinary cooperation: A Model Tumor Board in NSCLC
- Tissue Acquisition in NSCLC, Surgical and Interventional Radiology Perspectives
- Best Practices in Molecular Testing in NSCLC
- Patient Navigation: Role in Molecular Testing in NSCLC

Deliverables:

Deliverable	**Start Date:**	**To Be Completed by:**
Preparation of patient education handouts and electronic slide decks	January 1, 2013	May 1, 2013
Launch four live webinars	May 1, 2013	July 15, 2013
Discussion Boards	May 1, 2013	July 15, 2013
Post Archived Webinars	August 1, 2013	August 1, 2014
Post patient education handouts and electronic slide decks	May 1, 2013	August 1, 2014