D. Narrative: Molecular Testing and NSCLC Patients...Improving Efficacy, Enhancing Care

Lung cancer, the number one cancer killer in America, has been considered an aggressive, relentlessly progressive disease, with many patients diagnosed with advanced stage tumors and given few treatment options. Louisiana has the second highest rate of cancer mortality among the states (*Cancer Facts and Figures 2012*, ACS), and a high rate of death from lung cancer. To improve efficacy and enhance care for lung cancer patients, the Mary Bird Perkins – Our Lady of the Lake Cancer Center sustains an aggressive, holistic approach to program improvement, with the Lung Cancer Multidisciplinary Care Team providing leadership for high-quality, evidence-based care. Within a local community hospital, our Cancer Center's clinical research department currently oversees seven Phase II and Phase III clinical trials for NSCLC, including one that requires specific biomarkers for enrollment. We have been active in community tobacco cessation activities, including cancer in-patient cessation counseling and, starting November 5, 2012, we will be the first provider in Louisiana to offer a low-cost, low-dose CT scan (LDCT) program for adults at high risk for lung cancer, following NCCN Guidelines for Lung Cancer Screening (Version 1.2013). A focus on molecular testing to improve treatment for lung cancer patients is heavily aligned with both our mission and our dedication to improving patient care.

Advancing research in both drug development and genetic sequencing have converged to prompt a dramatic shift in lung cancer care, and clinicians must fully comprehend the different options for quality tissue assessment and how testing results impact treatment decisions—but within a dynamic environment of continued discoveries in genetic factors and new personalized treatment therapies based upon the molecular profiles of specific types of tumors.

1. Overall Aim: Our project will demonstrate a community hospital model for incorporating molecular testing, as recommended in national guidelines, to expand the use of targeted therapies for non-small cell lung cancer (NSCLC) patients. With "Improving Efficacy, Enhancing Care," the Mary Bird Perkins – Our Lady of the Lake Cancer Center focuses ultimately on improving personalized medical treatment to extend survival of NSCLC patients, especially those with late stage disease or recurrences. To shift clinical practice to new standards of care for lung cancer, our project addresses the automation of system processes and enhanced clinician knowledge and competencies. The science is complex, however, and the optimum outcome for lung cancer patients may depend upon the collaboration of several physicians who are each current on research, updated guidelines, the patient's history, and a detailed molecular profile of the tumor.

Our overall project goals are centered in
a) improving quality of care and treatment outcomes for lung cancer patients, based upon results of molecular testing, as recommended in the National Comprehensive Cancer Network (NCCN) Guidelines (Version 3.2012 or later) for adenocarcinoma, Large Cell, and NSCLS NOS cancers; and b) increasing physician adherence within a community oncology setting to NCCN guidelines for appropriate molecular testing and individualized treatment therapies for NSCLC.

Key Objectives:

Objective I. To enhance existing technology as a structural framework for screening, tissue assessment, reporting, and clinical decision-making for NSCLC patient care in compliance with NCCN recommended guidelines

To address the need for consistent, research-based molecular testing processes, especially as new tests and new biomarkers are identified, the MBP-OLOL Cancer Center will establish efficient, systematic procedures across our physician network for integrating molecular testing into treatment for NSCLC by incorporating enhancements within and among the hospital Electronic Medical Record (CERNER), pathology software (LigoLab), and Tumor Registry Abstract records (CNExT). Specifically, additions are intended to 1) ensure all lung patients are screened for indications for molecular testing, including auto calculation of the 14-day charge rule for Medicare patients; 2) create automatic fields for pathologists' comments regarding indications for molecular testing; 3) automate standardized sets for physicians to order molecular testing; 4) create built-in reports for quantitative and qualitative indicators around molecular testing and targeted therapies for NSCLC patients; and 5) incorporate additional fields for molecular testing results as part of Tumor Registry abstracts. Using technology to support a new norm within clinical practice at the Cancer Center will increase appropriate molecular testing for NSCLC patients, reduce turnaround times for test results and clinical decisions for treatment, and reduce the number of patients who "fall through the cracks."

Objective II. Demonstrate a minimum of 90 percent physician compliance with NCCN guidelines for molecular testing (EGFR and ALK) of NSCLC patients treated at the MBP – OLOL Cancer Center by the end of the project through chart audits performed by both the project manager and navigators in real-time with new technology enhancements rather than retrospectively

Multidisciplinary Care Teams (MDCs) regularly contribute to new initiatives and care standards as clinical leaders within the MBP-OLOL Cancer Center's comprehensive cancer program. Discussions within the Lung Cancer MDC in late 2011, along with physician questions about new therapies in Tumor Conferences, revealed inconsistencies across the physician network in regard to molecular testing and resulting personalized therapies. With oversight from the Lung Cancer MDC, our project focuses primarily on improving compliance with recent NCCN guidelines for appropriate molecular testing for epidermal growth factor receptors (EGFR) and anaplastic lymphoma kinase (ALK), ensuring consistency and quality across the continuum of care. (We acknowledge that some physicians will have individual, patient-specific reasons for alternative protocols). Our project will also help define supporting roles for patient navigators working with NSCLC patients who have orders for molecular testing.

Objective III. To improve clinical competencies in lung cancer standards of care across the professional, multidisciplinary physician network, from adequate tissue acquisition through diagnosis and treatment, by expanding access to high quality, professional education through approved Continuing Medical Education(CME), as well as through informal but structured

learning opportunities addressing new standards for NSCLC cancer care

Professional clinical education remains a priority in our goals to shift practice around recommended tissue assessments to target personalized therapies for lung cancers by surgeons, radiologists, pulmonologists, oncologists, and pathologists. Both Our Lady of the Lake Regional Medical Center and Mary Bird Perkins Cancer Center are accredited by the Louisiana State Medical Society to provide Continuing Medical Education to clinical staff. A minimum of four CME sessions will be developed for delivery during the grant period, offered to the estimated 50 hospital- and cancer center-affiliated physicians (surgeons, radiologists, pulmonologists, medical oncologists, and pathologists) in year one, with the inclusion of additional physicians seeing lung cancer patients throughout the region in year two. Physician leaders within the MBP – OLOL Cancer Center's Lung Multidisciplinary Care Team, with MDC staff support, will outline necessary content and approve learning objectives in collaboration with the CME Committee (see members of project leadership workgroup in Section C). Additional, less structured educational sessions are also planned, such as MDC presentations, "lunch and learns" or during Service Line Meetings and "town halls" routinely scheduled for hospital/medical staff to disseminate new standards of care, updated procedures, and other new information.

2. Technical Approach: The specific area of interest for the Pfizer grant RFP focuses on performing appropriate molecular testing to inform personalized treatment therapies for NSCLC patients to extend survivorship. Our project will focus on aligning clinician knowledge and Cancer Center Standard Operating Procedures (processes) with the latest NCCN guidelines for identifying lung patients for possible molecular testing (who to test), the points in the diagnosis and care continuum at which tests should be ordered (when to test), and the factors that drive the selection and order of molecular testing (how to test), starting with tests for epidermal growth factor receptor (EGFR) and anaplastic lymphoma kinase (ALK). Enhancements to electronic technology will support appropriate molecular testing and tissue assessment as standard practice across the physician network affiliated with the MBP – OLOL Cancer Center. As a result, patients with advanced non-small cell lung cancer whose tumors have specific genetic mutations may experience extended survivorship through targeted therapies that have greater efficacy than standard chemotherapy.

Our approach includes a clear responsibility for the Lung Cancer Multidisciplinary Care Team for overall quality assurance and deliverables. MDCs across the nation assume a strong role in identifying gaps in the continuum of cancer care and work to improve the coordination and quality of care. MBP-OLOL Cancer Center will create and evaluate a community hospital model for enhanced molecular testing and improved treatment therapies for NSCLC in a project that has been designed and will be driven by members of the Lung MDC.

Intra-organizational and Inter-organizational Roles to Meet Project Objectives (see Letters)

- **The applicant, Our Lady of the Lake Regional Medical Center (OLOL)**, was established in 1923 as part of the Franciscan Missionaries of Our Lady Health system, which includes several hospitals and affiliated health providers serving 1.8 million people in Louisiana. As the largest hospital in south Louisiana, OLOL has more than 700 licensed beds at its

main facility on 100 acres in the heart of Baton Rouge. We employ a staff of 5,000, with 1,000 affiliated physicians, and an 11-parish (county) primary service area. Each year, more than 35,000 patients are treated in the hospital, with 350,000 individuals seen through outpatient locations. Graduate medical education in partnership with Louisiana State University (LSU) is currently planned, including more than 110 medical residency positions to be activated by 2013. Residents in related medical specialties are slated to attend Multidisciplinary Care Teams and Tumor Conferences in the future, which will hardwire into physician training the multidisciplinary approach to cancer care. (LSU Head and Neck residents already attend and present at Head and Neck Tumor Conference.)

The MBP- OLOL Cancer Center, located on the hospital campus, was created as an integrated cancer program in 1988 and accredited by the American College of Surgeons Commission on Cancer in 1992. Treating over 2,200 **new** cancer patients annually, the center has a multidisciplinary approach to cancer treatment from diagnosis to survivorship or end-of-life care, providing surgery, chemotherapy, radiation therapy, a tumor registry, hormonal therapy, immuno-therapy, peripheral stem cell transplant, genetics, early detection, survivorship programming, and clinical research.

As a community hospital, with a broad coalition of clinicians representing different provider practice models serving on the Lung Cancer Multidisciplinary Care Team, OLOL will oversee all finances, contracts, and project deliverables, including CMEs, in collaboration with the MBP – OLOL Cancer Center leadership team, which oversees the integration, development, accreditation, and operations of the Cancer Center. The Principal Investigator (PI), Project Manager, and the MDC Team Manager, all hospital employees, will provide day-to-day management of the project to ensure timely completion of all deliverables.

- The Cancer Center's **Lung Cancer Multidisciplinary Care Team** improves the quality of cancer care and facilitates "mind sharing" among physician leaders, allied healthcare professionals, and other care providers who participate in our team approach to patient care. To provide oversight for grant deliverables, on time and as designed, an eight (8) member workgroup of Lung Cancer MDC members has committed to project leadership roles, including that of Principal Investigator. The complete Lung MDC and its support staff are, however, also committed to reaching the objectives as outlined above and will provide input toward the design of the software program enhancements, the content for professional education sessions, and efforts to ensure each member's "network of influence" is tapped for dissemination of new practice standards for lung cancer care. Attendees at the Lung Cancer MDC include 23 physicians representing private and public health providers (surgeons, radiologists, oncologists, pathologists, pulmonologists, and a molecular geneticist), a palliative care nurse practitioner, two clinical researchers, six patient navigators (nurses and social workers), and seven support staff and Cancer Center administrators.

  Oncology Solutions, a national oncology consulting firm, works with the Lung MDC under a contract with the MBP-OLOL Cancer Center staff to bring the latest updates in national treatment guidelines for Non-small Cell and Small Cell Lung Cancer

to Lung MDC Team physicians, emphasizing adherence to NCCN Clinical Practice Guidelines. Using these guidelines, the team will continue to conduct chart audits to measure adherence, develop quality studies and protocols around molecular testing, and implement molecular diagnostics into the standard of care for all lung patients, as appropriate. In collaboration with Oncology Solutions, the Lung MDC has made significant strides in the area of molecular medicine and will continue to do so with the assistance of the Pfizer grant. Pathologists working at the Cancer Center have embraced the need for improvements in pathological diagnosis and the importance of distinguishing histological subtypes in small biopsy specimens. Currently, however, all testing and reporting is manual and "paper-intensive," with nothing to automatically "trigger" physicians to consider molecular testing for each lung patient.

- **Mary Bird Perkins Cancer Center (**MBP) was established over 40 years ago as a community-owned radiotherapy provider in Baton Rouge, Louisiana, and now serves 18 parishes at five community treatment centers in southeastern LA. MBP operates comprehensive cancer centers through written agreements with three community hospitals, including the largest and most progressive cancer program at Our Lady of the Lake Regional Medical Center (OLOL). The leadership of MBP will support the project to improve adherence to NCCN molecular testing standards and resulting treatments through the Cancer Center LeadershipTeam, participation on the Lung MDC, and Cancer Center staffing. MBP will also connect the physician networks at its other comprehensive cancer programs with the educational opportunities offered through the proposed project in Baton Rouge, increasing the impact of the project on patient care in southeast Louisiana.

- Physicians from private practice groups (i.e., **the Pathology Group of Louisiana, CVT Surgical Center, and LA Hematology Oncology Associates**) have accepted roles for project leadership and professional education for pathology, surgery, and medical oncology (the P.I., a pulmonologist, is employed by **Critical Care Medicine Services,** which is owned by OLOL). Members of each practice will serve on the leadership workgroup, provide end-user feedback on technology enhancements, and review the content of related professional educational programming implemented as part of the project. Members of these physician groups will be available for presentations and informal and formal educational sessions, as well, serving as change agents for improved clinical practice for cancer care.

a. Current Assessment of Need

i. Gap analysis and Baseline Metrics: Tumor Registry data shows a total of 337 lung cancer patients (277 with NSCLC) treated at the MBP – OLOL Cancer Center in 2011. Since January 2012, the MBP-OLOL Tumor Registry has completed abstracts through March 2012 for an additional 92 cases of NSCLC. Among the 2011 cases and 2012 cases through March 2012, 64 percent were diagnosed with Stage III and Stage IV NSCLC.

Initial Review: The Lung Cancer Multidisciplinary Care Team invited Oncology Solutions,

national quality consultants, to make a presentation in late 2011 on updated NCCN guidelines for lung cancer treatment. The presentation highlighted molecular testing for EGFR, ALK, and KRAS as the standard of care for non-small cell lung cancer and included the results of a small percentage of chart audits that revealed NCCN recommended molecular testing was not consistent across the care continuum among clinical practices affiliated with the Cancer Center.

Chart Audit Results: Abstracted lung cancer tumor data from patients treated in 2011 and early 2012 were pulled this summer from Tumor Registry records and sent to pathology support staff, who ran manual reports from LigoLab on the selected cases based on histologic type. These reports also included recommendations by the pathologist for molecular testing and whether molecular testing was performed. Records on patients with a diagnosis of Adenocarcinoma, Large Cell or NSCLC NOS (N=198) were then analyzed by the Cancer Center's Biospecimen Program Manager. In 2011 and again in the first quarter of 2012, chart audits demonstrate that physicians ordered molecular testing for these 198 patients **only 28 percent of the time**. Because molecular testing was ordered at the same rate for these tumor types for all of 2011 and in the first 3 months of 2012, we conclude that we are not making significant progress in the number of clinicians who are ordering molecular testing in compliance with recent NCCN guidelines for NSCLC. Continuing to track this same metric as completed abstracts become available for the rest of 2012 will reveal any shifts in practice that have occurred before we start a new grant project under the Pfizer RFP. We will use any change in the rate of orders for molecular testing for Adenocarcinoma, Large Cell, or NSCLS NOS as our revised baseline at startup if the percentage varies from 28 % in more recently abstracted cases. As the project is implemented and enhancements are made to CERNER, we will be able to monitor the increase in molecular testing in real time, with daily reporting of this information possible.

The Lung MDC has continued to study articles focused on molecular testing, and in April 2012, adjusted specific language in regard to EGFR testing on the hospital's pathology report to note specific molecular testing rather than just "genetic testing" as labeled in the report at that time. The hospital pathologists also recently developed a manual process to attempt to fill the gaps for ordering molecular testing, but this method is too episodic and inefficient.

What we learned from surveying physicians: The issue around molecular testing expressed by physicians participating in the Lung MDC is the tedious, labor intensive, manual process that is in place during communication between the pathologist and the ordering physician regarding the type of lung cancer and diagnostic indications for appropriate molecular testing. Although pathology reports from LigoLab are uploaded as part of the EMR (CERNER) within 24 hours, if molecular testing is indicated, a physician has to fax or call the pathologist back to order the tests after reading the pathology report. The molecular testing results then are once again uploaded to an addended pathology report as part of the EMR. Our project will automate much of this process, with "triggers" to remind pathologists to indicate appropriate molecular testing as part of the pathology report, and a short menu of order sets planned for physicians to access easily.

ii. The **Primary Audience** directly benefitting from project outcomes are approximately 50 physicians and allied health staff providing care to lung cancer patients seen at the Mary

Bird Perkins – Our Lady of the Lake Cancer Center, as well as other physicians in southeast Louisiana who access continuing professional education opportunities. Medical specialists targeted for the project are pathologists, radiologists, medical oncologists, pulmonologists, and surgeons who evaluate and treat lung cancer patients. Ultimately, NSCLC patients with advanced disease and their families are the main beneficiaries of better treatment regimens that extend the lives of those with lung cancer through targeted therapies.

Measuring Engagement: From tumor registry abstracts, we will pull the names of physicians who ordered molecular testing for targeted NSCLC tumors at any time in 2012 and compare the list with additional physicians ordering molecular testing in 2013 and 2014. This is just one measure of engagement. The ultimate measure of physician and system engagement with technology enhancements and professional continuing education focused on better clinical decision-making will be improved adherence to NCCN guidelines for patient care as measured through on-going chart audits and new, real-time reporting functions that are complete and accurate. However, the Project Manager and PI will administer both structured and open-ended surveys with new knowledge and quality measures, starting with the Lung MDC and continuing with participants in CME and less formal learning sessions, to measure engagement with the project, including any changes in practice that result and any questions that remain for future study and presentation.

Attendance logs and sign in sheets will be maintained for meetings and sessions of the Lung MDC, the leadership workgroup, and professional clinical education, both CMEs and informal but structured presentations, to track consistent participation. As part of evaluation, chart audits will continue to demonstrate increased orders for molecular testing when indicated by the pathologist, as well as treatment with new therapies in line with results of EGFR and ALK testing. Status reports regarding progress toward the goals of "Improving Efficacy, Enhancing Care" will be regularly provided to the Lung MDC, Cancer Committee, the Leadership Team of the Cancer Center and to Cancer Centers affiliated with Mary Bird Perkins in other markets. In-house publications and E-news "magazines" will communicate the goals and outcomes of the project to stakeholders and the general public.

NCCCP: The most significant mechanism for disseminating project outcomes nationally is the network of hospital cancer centers participating in the National Cancer Institute's National Community Cancer Center Program (NCCCP). Now in its sixth year, NCCCP (http://ncccp.cancer.gov) continues to develop a tight network of 21 community hospitals in 16 states that are setting national standards for community cancer care. The goals of NCCCP are centered in improving quality cancer care for all, reducing healthcare disparities and increasing cancer research—especially access to clinical trials—with the ultimate goal of enhancing cancer care for patients close to home. Quality initiatives as part of NCCCP have built the capacity of the MBP – OLOL Cancer Center to design projects that ensure the latest evidence based standards of patient care, including projects focused on quality Biospecimen collection. In addition to an annual meeting allowing poster sessions and workshop presentations, all 21 community hospitals collaborate through a number of monthly telephone conference calls to share methods that improve patient care, including our participation in the project we propose.

b. Intervention Design and Methods

The goals of our proposal are centered in increasing appropriate molecular testing in the next year, as outlined in NCCN guidelines for Adenocarcinoma, Large Cell, and NSCLC NOS cancers, in order to improve treatment outcomes for lung cancer patients. Educational interventions, supported by infrastructure improvements to hospital technology, will facilitate improved clinical practice by expanding shared decision-making based upon a clear understanding of molecular testing and its impact on treatment choices. Educational content also addresses limitations of molecular tests and how testing for biomarkers can contribute to better diagnosis, prognosis, and treatment. Year One activities emphasize sound decision-making and procedures to ensure quality molecular testing and measuring improvements in adherence to NCCN guidelines (as updated during the grant period.) Year Two, based upon gains in Year One, will naturally progress to disseminating new research regarding the molecular tests for EGFR and ALK, as well as an emphasis on the approved targeted therapies.

MDC-suggested content for clinical education is grouped into four main categories for both Continuing Medical Education and informal presentations. "Lunch and Learn" and Service Line presentations will be especially targeted to the differing roles of medical specialties within lung cancer care. Clinical education will focus on

- Tissue collection and tissue assessment for NSCLC tumor types
- When molecular testing should be indicated in pathology reports, which tests should be performed, and in which order
- The interpretation of molecular testing results and their impact on treatment decisions
- NCCN recommended personalized treatment therapies to optimize outcomes for NSCLC patients.

Molecular Testing Starts with Proper Tissue Collection: Although the Cancer Center depends upon off-site testing for EGFR and ALK at seven accredited laboratories, we have effective quality control processes in place for all other in-house tissue assessment. Quality assurance for the pathology process is ensured by Pathology Group of Louisiana, which is CAP-certified. PGL pathologist Dr. Anthony Harton, who is also certified in Cytopathology, is the OLOL Director of Pathology and a physician leader in the design of our proposal (see CV in attachments).

A project that has greatly improved the capacity of the Cancer Center for quality tissue collection has been our participation as one of 25 sites in the Total Cancer Care (TCC) Consortium since 2008. On-site training by staff from H. Lee Moffitt Cancer Center early in the project and visits to the Moffitt Cancer Center by our pathology, pulmonology, and Biospecimen staffs has resulted in Standard Operating Procedures with high standards for tissue collection and banking. (The PI for our proposed project also serves as the PI for TCC.)

Through NCCCP, the Cancer Center has utilized the National Cancer Institute's *Best Practice for Biospecimen Resources.* Our community cancer center's robust tissue banking program has been a leader across the nation in both volume and quality. From 2009-2011, we have collected 944 total tissue specimens for TCC. In addition, the Cancer Center and Pathology Group of Louisiana (PGL) participated in an NCCCP initiative to document total fixation time in the surgical pathology report on all breast specimens; initial validation of HER2 IHC assay; and on-going participation in HER2 proficiency testing. We will, as part of our Pfizer project, monitor the quality of tissue collection for initial assessment and recommended molecular testing by

monitoring the percentage of cases in which the pathologist has to request more tissue. (In our assessment of all 2011 and first quarter 2012 cases, additional tissue for assessment was requested only one time in 198 cases)

Current Tissue Collection flow chart:
When frozen tissue is not required:
Patient consented→specimen collected, needle biopsy (radiology) or resection (surgery) →if no frozen section diagnosis needed, put in 10% formalin within 15 minutes in properly labeled (with patient name and MRN) container→transported to histology lab→recorded in LIS system and given unique barcode ID→tissue gross description recorded and transcribed into tissue report→tissue processed→tissue embedded→tissue block cut, slides made and stained with H&E stain→slides read by Pathologist→path report uploaded to CERNER within 24 hours

For frozen section diagnosis:
Patient consented→specimen collected and transported from surgery room to frozen section room and handed to Pathologist→Pathologist performs gross dictation to describe specimen→Pathologist mounts tissue on chuck and cuts tissue on cryostat→tissue mounted on to slides→slides stained and examined/read by Pathologist→Pathologist calls Surgeon in surgery room with preliminary findings→residual tissue is placed in formalin and transported to histology lab→then follows above process all the way from recording in the LIS system to path report uploaded in CERNER within 24 hours

Daily H&E stain quality controls performed by histology lab for batch of H&E stains and reviewed/signed by Pathologist

Recommendations for molecular testing by the pathologist, based upon analysis of the tumor/ tissue, are now included at the end of the path report. If the ordering physician agrees that molecular testing is appropriate, he or she will call or fax the pathologist with an order to perform molecular testing. At this time, all tissue samples are sent off site for molecular testing, which is the most pragmatic process for the number of tissue samples we process for molecular testing.

Equally important to the intervention design is the technology component for automating certain steps in the current tissue assessment process to reduce turnaround time; make it easier for physicians to access indications for molecular testing; and create a mechanism by which the Cancer Center can monitor testing and treatment decisions aligned with NCCN guidelines. Several initiatives illustrate this as a feasible and credible approach to improving care. We have already created a customized, in-house electronic system to improve patient navigation and track patients as they transition to different phases of care, with built-in quality reporting. Another similar strategy is the daily update delivered to the Biospecimen staff in real time as cancer surgeries are added to the surgery schedule so patient consent forms for tissue removal is assured before each surgery.

Using these experiences, we are ready to significantly impact practice in the use of biomarkers to personalize treatment therapies of NSCLC patients with advanced cancer. Our Lung MDC workgroup has outlined a timeline and work plan that addresses two simultaneous

sets of activities upon grant award: changes to the EMR, CNExT, and LigoLab (pathology) reporting system to facilitate system integration of procedures to integrate molecular testing and treatment protocols according to NCCN standards, and finalizing additional processes to determine exactly what gaps in knowledge are responsible for the relatively low molecular testing rates for our patients with late stage NSCLC.

c. Evaluation Design

Evaluation questions will focus on the purpose, objectives, and activities as outlined above in the project design. Auban Burr (MBA), current Biospecimen manager for Cancer Center projects, will direct evaluation and data collection in her role as Project Manager, with support from the leadership workgroup from the Lung MDC. Percentage of select tumors assessed for molecular testing as indicated by the pathologist will be added to the Lung MDC dash board created and reported as part of our NCCCP project. Evaluation will include both quantitative and qualitative measures that are summative as well as formative. Additional evaluation activities as requested by the funder are also considered part of evaluation.

i. Among the practice gaps identified is the low percentage (28 %) of molecular tests ordered in 2011 and the first quarter of 2012 for patients diagnosed with Adenocarcinoma, Large Cell, and NSCLC NOS cancers. We will repeat the same process used to ascertain the baseline percentage, using 2013 and 2014 data obtained from the Tumor Registry to show improvement in the rate of appropriate molecular testing for EGFR and ALK. In addition, we will be able to pull reports from LigoLab and CERNER (the EMR) in real time to monitor the percentage of patients for whom molecular testing was indicated by pathology and ordered appropriately by the physician diagnosing or treating the patient. Elements within this metric include: when molecular testing was not performed for these types of cancers—did the pathologist's report recommend molecular testing (or consideration of molecular testing)? And did the physician submit follow up orders for molecular testing when indicated in the pathology report? A sample of those cases for which the pathologist indicates molecular testing that was never ordered will be selected to follow up with physicians treating those patients to learn more anecdotal information as to why molecular testing was not performed.

As part of on-going assessment to be folded back into project implementation is a quarterly report on exactly which personalized therapies are being prescribed as a result of EGFR or ALK testing results; which oncologists are incorporating personalized therapies into the treatment regimen; and which oncologists are confining treatments to traditional therapies. This information will drive new interventions as part of the project, as well as allow us to collect perceptions regarding patient outcomes from physicians utilizing new targeted therapies.

To evaluate the quality and effectiveness of enhancements to the EMR, LigoLab, and CNExT systems, the following are among the evaluation questions we will present to the leadership team, members of the Lung MDC, other physician end-users, and programmers creating the new functions.

1. Was input from end-users incorporated and adequate for a satisfactory product?
2. Does each system function with upgrades as requested and indicated in the scopes of work?
3. Do reporting functions provide the information needed for quality assurance and quantitative tracking? Are reports easily accessed or are there burdensome steps required?
5. How easy are new functions to use for pathologists? Ordering physicians? Evaluator?
6. Was training for end users adequate?

7. What percentage of end users actually access and utilize the new functions of the EMR and LigoLab within 90 days of completion?
8. Do additions to the Tumor Registry abstracts allow reports for each field added?
Others will be developed as the project rolls out.

Evaluation of professional clinical education will focus on the stated learning objectives for each presentation, both CME and less formal formats, at the time of the educational activity, as well as audits of patient records to measure shifts in the frequency of molecular testing for the targeted tumor types and for increases in approved personalized therapies as recommended in NCCN guidelines. Open-ended and structured surveys will be collected from participants to rate the quality of the content and its usefulness for patient care.

ii. Sources of data are patient charts, pathology reports, and real-time EMR information once enhancements are complete; automated LigoLab reports; Tumor Registry abstract information, to include reports listing cases for which molecular testing was ordered and resulting treatment with molecular targeted therapies as recommended in NCCN guidelines. Additional data sets for quality of our educational intervention, besides analysis of how practice within the cancer continuum changes, will be participant surveys about suitability of content and new information to be incorporated into treatment decisions. We will also work closely with lung patient navigators to outline and submit an analysis of effective roles for navigators in the follow-up/monitoring of cases for which molecular testing has been offered.

iii. Data collection will be scheduled and managed by the Project Manager under the supervision of the PI. Staff from the Pathology Group of Louisiana will run LigoLab reports on the cases identified through Tumor Registry data for NSCLC patients.

iv. A control group is not currently planned but most metrics involve changes in behavior that are a result of technology enhancements and educational interventions. These can be measured against the baseline data we have collected thus far. We will be able to track metrics in real time to alter our approach if needed. We cannot control for new knowledge that is acquired outside our "sphere of influence;" instead, we honestly hope that our physicians gain new, accurate knowledge of molecular testing and resulting treatment choices from other available sources and share freely what they know to improve outcomes for cancer patients.

3. Detailed Work plan and Deliverables (see also attached Work plan)

The work plan will be implemented by the leadership workgroup--eight members of the Lung Cancer Multidisciplinary Care Team who have committed to the project designed in response to the Pfizer Medical Education Request for Proposals. Monthly meetings of the complete membership of the Lung MDC will provide opportunities to report on grant activities, recruit additional volunteers for specific tasks, disseminate educational opportunities for physician member's practices, and collect new peer-reviewed journal articles on topics related to emerging genetic discoveries and/or new targeted therapies that should be considered for educational content when CMEs and informal education events begin in the third quarter of Year One.

Weekly meetings of the workgroup during the first quarter, called by the PI, will ensure a smooth start up and serve to identify and obtain additional metrics to be used to finalize educational content and the evaluation plan. The first six months of the proposed project will focus on technology enhancements, preparing workshop materials, and completing paperwork for CMEs. Monthly LigoLab reports in real-time will be presented at the workgroup meetings, starting with the second quarter and continuing for the duration of the grant. These reports will show how many adenocarcinoma, Large Cell, and NSCLA NOS cancers were identified and indicated for molecular testing in the pathology report and how many resulting physician orders were requested. The number of molecular tests ordered in response to pathologists' recommendations will be tracked and charted per month from Month 4 through Month 24.

The PI will provide oversight for all activities, with strong support from the project manager and MDC Team Manager. The project manager (.4FTE), in collaboration with the workgroup, will direct efforts that will result in new technology functions to support improved used of molecular testing for EGFR and ALK to personalize patient treatment regimens. Most additions to CERNER, LigoLab, and CNExT will all be completed by the end of the second quarter, with training for all end users (physicians, physician staff members, and hospital staff) delivered by hospital IT staff. CERNER enhancements will continue to be tweaked and improved, based upon user feedback, until the second year of the grant period.

Content for pathology educational sessions will be developed by the Chief of Pathology (Dr. Harton), while content for medical oncologists will be outlined and delivered by Dr. David Hanson no later than the third and fourth quarters of Year One. It is assumed that new clinical trials, new biomarkers, and new drug therapies will be added to educational sessions as national guidelines are revised with approved testing and targeted therapies. Activities in Year Two will be concentrated on educational interventions and continued tracking of outcomes, especially the progress toward compliance with NCCN guidelines for molecular testing (the focus for Year One) and recommended targeted therapies (the focus for Year Two). The physician network of the MBP – OLOL Cancer Center will be the population targeted for education in Year One, while radiologists, pathologists, medical oncologists, surgeons, and pulmonologists throughout the region treating patients for lung cancer are the focus in Year Two. CME delivered in Year One may also be replicated in Year Two for physicians as needed.

The activities undertaken for this project will lay the foundation for addressing the needs in the future for additional genetic and molecular testing as science continues to expand what we know about the biology of cancer and cancer tumors. The Cancer Center will develop a model for personalized cancer that will be useful for other applications and other cancers.

Work Plan	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Quarter 5	Quarter 6	Quarter 7	Quarter 8
Technology Deliverables								
Deliverable Number 1: LigoLab enhancement to ensure all lung patients are screened for indications for molecular testing, including auto calculation of the 14-day charge rule for Medicare patients	**Complete**							
Deliverable Number 2: LigoLab enhancement to create automatic fields for Pathologists' comments regarding indications for molecular testing	**Complete**							
Deliverable Number 3: CERNER enhancement to automate standardized sets for physicians to order molecular testing and targeted therapies for NSCLC patients	In Progress	In Progress	**Complete**					
Deliverable Number 4: CERNER enhancement to create built-in reports for quantitative and qualitative indicators around molecular testing and targeted therapies for NSCLC patients	In Progress	In Progress	In Progress	In Progress	In Progress	**Complete**		
Deliverable Number 5: Incorporate additional fields for molecular testing results as part of Tumor Registry abstracts	**Complete**	Utilized for Evaluation	Utilized for Evaluation	Utilized for Evaluation	Utilized for Evaluation	Utilized for Evaluation	Utilized for Evaluation	Utilized for Evaluation
Process/Quality Deliverables								
Deliverable Number 6: Obtain commitments for Leadership Workgroup; begin weekly meetings to establish assigments, outline content for educational intervention and evaluation metrics; monitor progress and plans for information dissemination	**Complete**	Team to meet weekly	Parts of team to meet every other week, or as needed	Parts of team to meet every other week, or as needed	Parts of team to meet every other week, or as needed	Parts of team to meet every other week, or as needed	Parts of team to meet every other week, or as needed	Parts of team to meet every other week, or as needed

Deliverable Number 7: Add molecular testing metrics to the present at Lung MDCs and Cancer Committees	**Complete**	Utilized for Evaluation	Utilized for Evaluation	Utilized for Evaluation	Utilized for Evaluation	Utilized for Evaluation	Utilized for Evaluation	Utilized for Evaluation
Deliverable Number 8: Add molecular testing metrics to Cancer Program's Lung Dashboard	**Complete**	Utilized for Evaluation	Utilized for Evaluation	Utilized for Evaluation	Utilized for Evaluation	Utilized for Evaluation	Utilized for Evaluation	Utilized for Evaluation
Deliverable Number 9: Demonstrate 90% compliance with the NCCCN Guidelines for molecular testing indications of targeted therapies of NSCLC patients by project completion	In Progress	In Progress	In Progress	In Progress	In Progress	In Progress	In Progress	**Complete**
Educational Intervention Deliverables								
Deliverable Number 10: Hold 4 CMEs to educate physicians and allied health staff on system wide changes in both informatics and molecular testing for targeted therapies	Planning Period	Planning Period	1st CME	2nd CME	Evaluation of Year One CMEs	3rd CME	4th CME	Evaluate and **Complete**
Deliverable Number 11: Create presentation materials, schedule, implement and evaluate Lunch and Learns, MDC presentations, Service Line and town meetings for physician education and compliance to most current NCCN guidelines for NSCLC and molecular testing	Planning Period	Planning Period	Hold 7	Hold 6	Evaluation of Year One Lunch and Learns and Plan Year Two Lunch and Learns	Hold 7	Hold 6	Evaluate and **Complete**