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Prospective Assessment of the Value of Genomic Profiling in Metastatic Lung Cancer

Background/Objectives:

• Metastatic lung cancer is a major cause of death worldwide
• Genomic alterations are common in non-squamous histologies and may be targetable with medications resulting in dramatic prolongations in survival
• Testing rates for genomic alterations are suboptimal for both common (detectable by cheaper technologies) and uncommon alterations (detectable by more expensive next-generation-sequencing)
• Use of targeted agents is suboptimal for uncommon genomic alterations, even when “off-label” medications are available, especially in non-academic centers
• Economic and clinical outcomes may vary by genomic profile, and are not well understood
• This prospective observational study is designed to reveal genomic profiling patterns and the influence of testing on clinical and economic outcomes among patients with advanced lung cancer in real world settings

Relevant Population:

• All previously untreated metastatic lung cancer patients treated at COTA centers throughout New Jersey USA (academic and community centers)
• Pure observational study, no influence by COTA on testing rates or use of targeted therapy
**Proposed and Completed Actions:**
- Data collection started April 2015
- Project registered with clinicaltrials.gov (NCT02671045)
- Preliminary analysis conducted September 2016: 407 patients enrolled (343 non-squamous histologies)

**Results/Impact:**
- 123 patients have undergone next-generation sequencing (34% of non-squamous patients). Alterations of EGFR and ALK have been identified in 15% of non-squamous histology patients
- Genomic alterations with potentially targetable (but non-approved) agents noted in 5% of non-squamous histology patients
- 12% of all non-squamous histology patients have received targeted therapies; 76% of EGFR/ALK patients received targeted therapies; only 16% of patients with “rare” alterations received “off-label” or experimental therapies.
- Prior retrospective analysis at the same centers (>800 patients) demonstrated median survival rates of 15 months in metastatic lung cancer patients without genomic targets receiving conventional chemotherapy compared to 44 months for patients with mutations who received targeted therapy
- Preliminary impressions from the current observational study suggest that genomic profiling is able to identify a sizeable population of patients with advanced lung cancer who harbor “actionable” targets, with potential for improving survival.
- Preliminary impressions however also suggest that in the community setting access and/or utilization of “off-label” or experimental therapies is suboptimal.
- Total cost of care by testing patterns and treatments will be explored in future analysis

**Partners:**
Foundation Medicine, Horizon Blue Cross Blue Shield of New Jersey, Regional Cancer Care Associates
**What support:**
Translation of learnings to broader populations with attention to improving access and utilization of both genomic profiling and "off-label" targeted therapies (both on and off clinical trials).