For Physicians:
How to Discuss Biomarker Testing Results on LUNGMAP

Edited for this study from information available at
http://www.cancer.gov/cancertopics/pdq/genetics/overview/healthprofessional

Your patient has enrolled in the study "LUNGMAP: A Master Protocol to Evaluate Biomarker-Driven Therapies and Immunotherapies in Previously-Treated Non-Small Cell Lung Cancer (Lung-MAP Screening Study)."

As part of this study, your patient has undergone biomarker testing to look for genetic alterations (e.g., mutations, changes in gene expression) that may be targeted with a specific drug.

There is some evidence that targeted treatments may have a better chance of treating certain cancers and may result in fewer treatment-related side effects.

What results are available from the LUNGMAP panel?

The biomarker testing done in LUNGMAP, a next-generation sequencing panel, is ***somatic testing*** of tumor tissue:

- Somatic mutations can occur in any of the cells of the body except the germ cells (sperm and egg).
- Somatic mutations are not passed on to children.
- Somatic mutations can (but do not always) cause cancer and other diseases.
- Somatic testing of tumor tissue or blood is not ***germline testing*** of hereditary mutations, which are passed on from parent to child. Germline testing is not done in this study.

The somatic testing done in this study detects several types of genetic alterations. Possible findings include:

- **Deleterious mutations.** These are genetic variants that are known to disrupt protein function. Deleterious mutations can be found in genes related to tumorigenesis, but also in genes with unclear relevance to cancer.
- **Variants of uncertain significance.** These are genetic variants with unclear medical implications. These variants may or may not disrupt protein function or other cellular processes.
- **Tumor mutational burden (TMB).** This is a quantitative assessment of total somatic mutations per megabase of genome.
- **No detectable abnormalities.**

The attached report contains detailed information about the genetic mutations evaluated in this study. The initial section of the report provides information about cancer-related alterations. The remaining sections describe other results from the full LUNGMAP panel.

What will be done with these results?

Results from the LUNGMAP panel will be used to assign your patient to a treatment sub-study. Patients will be assigned to a biomarker-driven sub-study if their LUNGMAP panel results meet the biomarker eligibility definition for a biomarker-driven sub-study that is actively accruing. If there is an actively accruing non-match sub-study, patients not eligible for an actively accruing biomarker-driven sub-study based on the LUNGMAP panel results will be assigned to that non-match sub-study. To enroll onto any of these sub-studies, the specific eligibility criteria will need to be evaluated to determine if the patient can be registered to that sub-study.

What are some of the questions your patient may have?

Do these results have any implications for my family? The type of genetic testing done in this study (somatic testing) does not have any known significance for the other individuals in the patient's family.

Can these results be used by my insurance company or employer? There are laws designed to protect against the misuse of genetic information, but they may not give full protection. The Genetic Information Nondiscrimination Act of 2008, also known as GINA, was passed by Congress to protect Americans from such discrimination. This law prohibits health insurers and employers from using genetic information to discriminate against individuals. However, GINA does not cover life insurance, long-term care insurance, and disability insurance.

Who can I contact if I have questions? Contact the Study Chairs via LUNGMAP@swog.org