

## FAST FACTS

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### **LungMAP: A MASTER PROTOCOL TO EVALUATE BIOMARKER-DRIVEN THERAPIES AND IMMUNOTHERAPIES IN PREVIOUSLY-TREATED NON-SMALL CELL LUNG CANCER** (Lung-MAP Screening Study)

#### **Registration**

##### **Step 0:**

1. Patients with adequate archival tissue or a qualifying commercial FoundationOne CDx report should be registered directly to Step 1, without registering to Step 0. Patients who will submit tumor tissue from a new biopsy (not archival tissue) must also submit whole blood for ctDNA testing collected within +/- 7 days of the biopsy, preferably the same day (see Section 15.3). These patients must be registered to Step 0 in OPEN to obtain a patient ID number for the whole blood submission.  
Patients registered to Step 0 are not registered to the LUNGMAP protocol. To participate in LUNGMAP (including submission of tissue obtained from the new biopsy), patients must be registered to Step 1 in OPEN after evaluation of patient eligibility, including tumor tissue adequacy, per protocol Section 5.1, Step 1. The same SWOG patient ID number must be used.

##### **Step 1:**

1. Patients must have pathologically or cytologically proven non-small cell lung cancer (NSCLC; all histologic types). Patients must have Stage IV disease as defined in Section 4.0, or recurrent/progressive disease without a curative treatment option available. Mixed NSCLC histologies, are acceptable, but any known component of small cell lung cancer is not allowed.
2. Patients must either have progression on prior systemic treatment or have received at least one dose of systemic treatment as defined below: These criteria are:
  - a. Screening at progression on prior treatment:  
To be eligible for screening at progression, patients must have received at least one line of systemic therapy for any stage of disease (Stages I-IV) and must have progressed during or following their most recent line of therapy.
    - For patients whose prior therapy was for Stage IV or recurrent disease, the patient must have received at least one line of a platinum-based chemotherapy regimen and/or anti-PD-1/PD-L1 therapy, alone or in combination.
    - For patients whose prior systemic therapy was for Stage I-III disease only (i.e. patient has not received any systemic treatment for Stage IV or recurrent/progressive disease), disease progression on platinum-based chemotherapy must have occurred within one year from the last date that patient received that therapy. For patients treated with anti-PD-1 or anti-PD-L1 therapy for Stage I-III disease, disease progression on consolidation anti-PD-1 or anti-PD-L1 therapy must have occurred within one year from the date of initiation of such therapy. If disease progression was greater than one year after prior therapy, patients must receive subsequent systemic therapy to be eligible.
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OR

b. Pre-Screening prior to progression on current treatment:

To be eligible for pre-screening, patients must have received at least one dose of a systemic regimen for Stage IV or recurrent/progressive disease and must be prior to progression on this regimen.

Patients must have previously received or currently be receiving a platinum-based chemotherapy regimen and/or anti-PD-1/PD-L1 therapy alone or in combination.

Note: Patients will not receive their sub-study assignment until they progress and the LUNGMAP Notice of Progression is submitted.

3. Patients must either have adequate tissue available to submit on-study or have a prior known commercial FoundationOne CDx tissue-based (not liquid) tumor test for biomarker profiling. All other previous next-generation DNA sequencing (NGS) results will not be accepted.

1. Submitting tissue for on-study biomarker profiling: Patients must have adequate tumor tissue available, defined as  $\geq 20\%$  tumor cells and  $\geq 0.2$  mm<sup>3</sup> tumor volume.

- The local interpreting pathologist must review the specimen.
- The pathologist must sign the LUNGMAP Local Pathology Review Form confirming tissue adequacy prior to Step 1 registration.

Specimens from bone biopsy are not allowed unless the specimen is entirely soft tissue or has not been decalcified. All other sites of tumor are acceptable, given the specimen meets all requirements for tissue adequacy.

A formalin-fixed and paraffin-embedded (FFPE) tumor block or unstained FFPE slides 4-5 microns thick must be submitted. If slides are to be submitted, at least 12 unstained slides plus an H&E stained slide, or 13 unstained slides must be submitted. However, if slides are to be submitted, it is strongly recommended that 20 unstained slides be submitted.

Patients must agree to have this tissue submitted to Foundation Medicine for common broad platform CLIA biomarker profiling (see Section 15.2).

If archival tumor material is exhausted, then a new tumor must be obtained. Patients who submit tumor tissue from a new biopsy must also submit whole peripheral blood for ctDNA testing (see Section 15.3).

Patients must agree to have any leftover tissue (tissue that remains after biomarker testing) retained for the use of correlative studies outlined in the sub-study consents.

OR

2. Submitting commercial FoundationOne CDx results for reanalysis:

Patients must have a FoundationOne CDx report available with the following information:

- Results done on solid tumor tissue (liquid test not allowed)
- Original report date on or after September 1, 2019
- FMI Test Order # (e.g. ORD-1234567)

Patients must consent to have their commercial FoundationOne CDx test results disclosed to SWOG Cancer Research Network (see Section 15.2b).

4. Patients with known EGFR sensitizing mutations, EGFR T790M mutation, ALK gene fusion, ROS1 gene rearrangement, or BRAF V600E mutation are not eligible unless they have progressed following all appropriate standard of care therapy/therapies (in the investigator's opinion). EGFR/ALK/ROS1/BRAF testing is not required prior to Step 1 registration, as it is included in the LUNGMAP Foundation Medicine biomarker profiling.
5. Patients' most recent Zubrod performance status must be 0-1 (see [Section 10.2](#)) and be documented within **28 days** prior to Step 1 registration.
6. Patients must be  $\geq 18$  years of age.

7. Patients must also be offered participation in banking for future use of specimens as described in [Section 15.0](#).
8. Patients must be willing to provide prior smoking history as required on the LungMAP Onstudy Form.
9. As a part of the OPEN registration process (see [Section 13.4](#) for OPEN access instructions) the treating institution's identity is provided in order to ensure that the current (within 365 days) date of institutional review board approval for this study has been entered in the system.
10. Patients must be informed of the investigational nature of this study and must sign and give written informed consent in accordance with institutional and federal guidelines.

HIGH-LEVEL SCHEMA

