Cancer Research Consortium of West Michigan
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FAST FACTS

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

Registration

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 screening patients with known RET fusion positive NSCLC see S1900F and Section 18.6.
   - For patients with known EGFR mutation positive NSCLC that are screeningfor entry on **S1900G** please refer to see Section 18.7.
   - For patients whose prior therapy was for Stage IV or recurrentdisease, the patient must have received at least one line of astandard of care therapy for Stage IV or recurrent disease (See current NCCN guidelines).
   - For patients who received adjuvant chemotherapy, progression must have occurred within **one year** from last date that patient received that therapy. For patients receiving adjuvant osimertinib, disease progression must have occurred on osimertinib. 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 therapymust have occurred within **one year** form the date of initiationof such therapy. If disease progression was greater than oneyear after prior therapy, patients much receive subsequent systemic therapy to be eligible.
   - 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 initiationof such therapy. If disease progression was greater than one year after prior therapy, patients must receive subsequent systemic therapy to be eligible.

OR

3. 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 received or currently be receiving a first-line standard of care therapy.

It is strongly recommended that patients receiving osimertinib do not pre-screen due to the **S1900G** eligibility (See **S1900G** Section5.1.c).

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

b. Patients must meet one of the following criteria:

- Patient has adequate tissue available to submit for on-study biomarker profiling (See Section 5.1.c.1)
  Note: For patients with known EGFR mutation positive NSCLC that are screening for entry into **S1900G**, the tissue specimen must have been obtained after radiographic or clinical progression on osimertinib.

- Patient has prior commercial FoundationOne CDx tissue-based (not liquid) tumor test results (See Section 5.1.c.2)
  Note: For patients with known EGFR mutation positive, MET amplification positive NSCLC that are screening for entry into **S1900G**, the tissue specimen must have been obtained after radiographic or clinical progression on osimertinib.

- Patient has documentation of prior known EGFR mutation positive, MET amplification positive NSCLC. (See Section 18.7.b).
- Patient has documentation of prior known MET exon 14 skipping positive NSCLC (see section 18.8b)

1. Submitting tissue for on-study biomarker profiling: Patients must have adequate tumor tissue available, defined as ≥ 20% tumor cells and ≥ 0.2 mm3 tumor volume.
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 biopsy must be obtained
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-1234567-01)
Patients must consent to have their commercial FoundationOne CDx test results disclosed to SWOG Cancer Research Network (see Section 15.2a).

4. Patients' most recent Zubrod performance status must be 0-1 (see Section 10.2) and be documented within **28 days** prior to registration.

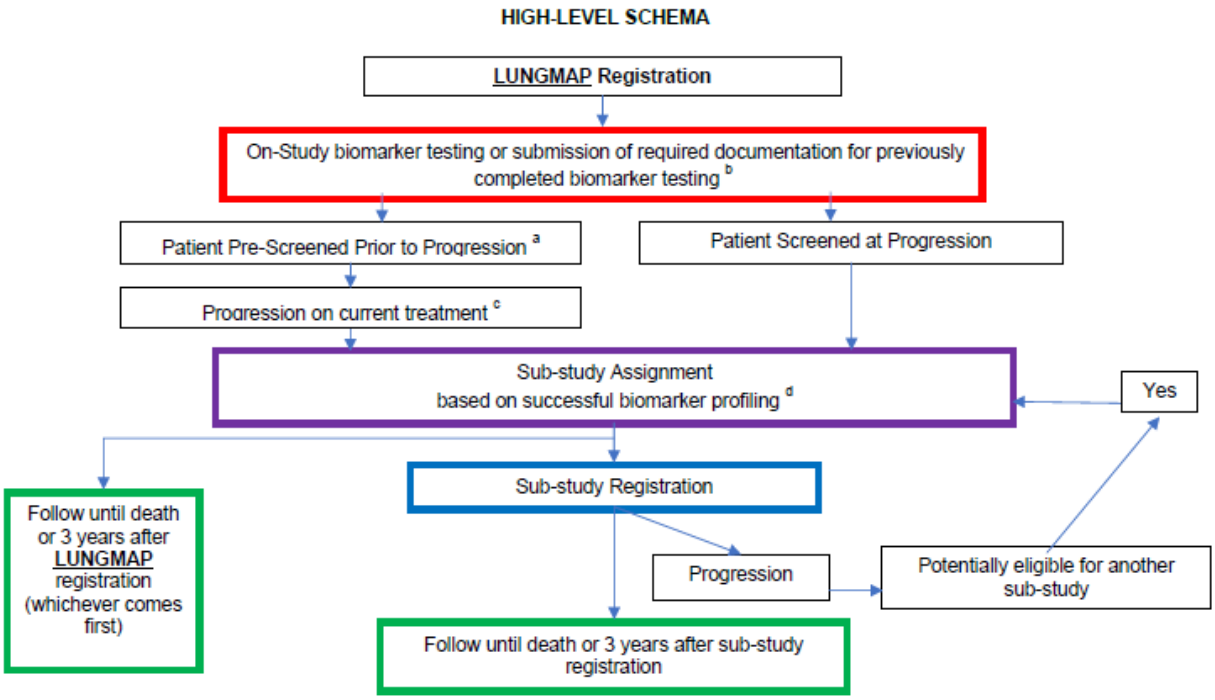
5. Patients must be ≥ 18 years of age.

6. Patients must also be offered participation in banking for future use of specimens as described in Section 15.0 .

7. Patients must be willing to provide prior smoking history as required on the LungMAP Onstudy Form.

8. 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.

9. 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.



[a] See Section 5.1b2 for details on pre-screening.

[b] See Section 5.1c, 7.1, 15.2, 18.6, 18.7, and 18.8 for details.

[c] Notice of progression must be submitted. See Section 5.1b2, 7.1, 14.4i, and 18.1a for more details.

[d] Notification of sub-study assignment will be sent by email. See Section 7.1 and 18.1a