

## 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)**

#### **5.0 ELIGIBILITY CRITERIA**

A list of Lung-MAP sub-studies can be found at the following location <https://www.swog.org/lung-map-resources>. This is meant to be a snapshot and sites must continue to reference the appropriate sub-study protocol to confirm the most up-to-date and complete information.

#### **5.1 Disease Related and General Criteria**

- a. Participants must have pathologically or cytologically proven non-small cell lung cancer (NSCLC). Mixed histologic subtypes of NSCLC are acceptable, but any known component of small cell lung cancer is not allowed.
- b. Participants must have Stage IV NSCLC, or recurrent or progressive NSCLC without a curative treatment option available.
- c. Participants must be  $\geq 18$  years of age.
- d. Participants' most recent Zubrod/ECOG performance status must be 0–2 and be documented within **28 days** prior to registration.
- e. Participants must be eligible to be **Pre-Screened** prior to progression (see [Section 5.2](#)) or **Screened at Progression** (see [Section 5.3](#)) or **Enrolled with Treatment- Naïve NSCLC and a Designated Targetable Alteration** (if sub-studies allowing treatment-naïve participants are open at the time of registration, see [Section 5.4](#)).

#### **5.2 Pre-Screening Eligibility Criteria**

- a. To be eligible to be pre-screened, participants must have tumor tissue available for on-study biomarker profiling and must meet both of the following criteria:
  - 1) Participants must be prior to progression on their current or most recent systemic treatment for Stage IV or recurrent/progressive NSCLC, AND
  - 2) Participants must have previously received or currently be receiving a first-line standard of care therapy for Stage IV or recurrent/progressive NSCLC. Participants may have received multiple lines of therapy for Stage IV or recurrent/progressive NSCLC.

**NOTE:** Participants using previously completed biomarker test are not eligible to be Pre-Screened and must only register to be Screened at Progression. See Section 5.3.

**Sub-study assignments are provided for Pre-Screened participants when the LUNGMAP Notice of Progression Form is submitted in RAVE.**

Participants receiving osimertinib interested in participating in **S1900G** must not be pre-screened and will need a post-progression assessment of MET amplification status (on tissue or blood) due to the **S1900G** eligibility (see **S1900G** section 5.1.c).

### 5.3 Screening at Progression Eligibility Criteria

a. To be eligible to be screened at progression, participants must meet the following criteria for prior treatment of NSCLC. Specifically, participants:

- 1) Must have received at least one line of systemic standard of care therapy for Stage I-IV NSCLC, AND
- 2) Must have progressed during or following their most recent line of systemic therapy for NSCLC, AND
- 3) If participant has not received any prior systemic therapy for Stage IV or recurrent/progressive NSCLC, disease progression on prior systemic therapy for Stage I-III disease must have occurred within ( $\leq$ ) **180 days** from the last date that participant received that therapy. If disease progression was greater than ( $>$ ) **180 days** after the last dose of therapy for stage I-III disease, participants must receive standard-of-care therapy for stage IV or recurrent/progressive disease and experience disease progression during or after this therapy to be eligible.

b. To be eligible to be screened at progression, participants must meet one of the following criteria for biomarker testing:

- 1) have tumor tissue available for on-study biomarker profiling, OR
- 2) have documentation of a previously completed Next Generation Sequencing (NGS) test on the list of approved tests (see the **LUNGMAP** NGS Testing Reference Page at <http://www.swog.org/lung-map-resources>), OR
- 3) have documentation of a previously completed NGS test not on the list of approved tests, have submitted a report to [LUNGMAPNGS@swog.org](mailto:LUNGMAPNGS@swog.org) for review, and have an e-mail documenting the test is acceptable (see Section 15.4), OR
- 4) Have documentation of the presence of a specific biomarker (or set of biomarkers) for one of the biomarker-driven sub-studies open at the time of registration and have

submitted a report to [LUNGMAPNGS@swog.org](mailto:LUNGMAPNGS@swog.org) with an e-mail documenting that the test is acceptable (see Section 15.4).

**NOTE:** For participants 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.

#### 5.4 Enrolling with Treatment-Naïve NSCLC and a Designated Targetable Alteration

- a. Participants with documentation of the presence of a specific biomarker (or set of biomarkers) for one of the biomarker-driven sub-studies open to treatment-naïve participants at the time of registration (see **LUNGMAP** Sub-study Reference Table at <http://www.swog.org/lung-map-resources>) are eligible if participants meet the following criteria. Specifically,
- 1) Participants must not have received any systemic therapy for Stage IV or recurrent NSCLC, **AND**
  - 2) Participants must have documentation of the presence of a specific biomarker (or set of biomarkers) for one of the biomarker-driven sub-studies open to treatment-naïve participants at the time of registration (see **LUNGMAP** Sub-study Reference Table at <http://www.swog.org/lung-map-resources>) through ONE of the following mechanisms:
    - i. Participants must have documentation of a previously completed Next Generation Sequencing (NGS) test on the list of approved tests (see the **LUNGMAP** NGS Testing Reference Page at <http://www.swog.org/lung-map-resources>), **OR**
    - ii. Participants must have documentation of a previously completed NGS test not on the list of approved tests, have submitted a report to [LUNGMAPNGS@swog.org](mailto:LUNGMAPNGS@swog.org) for review, and have an e-mail documenting the test is acceptable (see [Section 15.4](#)), **OR**
    - iii. Participants must have documentation of the presence of a specific biomarker (or set of biomarkers) for one of the biomarker-driven sub-studies open to treatment-naïve participants at the time of registration and have submitted a report to [LUNGMAPNGS@swog.org](mailto:LUNGMAPNGS@swog.org) with an e-mail documenting that the test is acceptable (see [Section 15.4](#)).

#### 5.5 Specimen Submission for On-Study Biomarker Profiling Criteria

a. For participants submitting tissue for on-study biomarker profiling, all of the following criteria must be met:

- A formalin-fixed and paraffin-embedded (FFPE) tumor block, or at least 12 unstained slides plus an H&E-stained slide or 13 unstained FFPE slides 4-5 microns thick must be available for submission, **AND**
- Participants must agree to have this tissue submitted to Foundation Medicine for common broad platform CLIA biomarker profiling (see Section 15.3a), **AND**

- Participants must agree to have any leftover tissue (tissue that remains after biomarker testing) retained for the use of future correlative studies, AND
- The tumor sample must have  $\geq 20\%$  tumor cells and  $\geq 0.2$  mm<sup>3</sup> tumor volume, AND
- The tumor sample must not be from a bone biopsy 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.

**NOTE:** Liquid specimens like pleural fluid are acceptable if they meet cellularity requirements and are mounted on an FFPE block.

### 5.6 Prior Biomarker Test Submission Criteria

a. For participants providing documentation of a previously completed test on the list of approved tests/laboratories, ALL of the following criteria must be met:

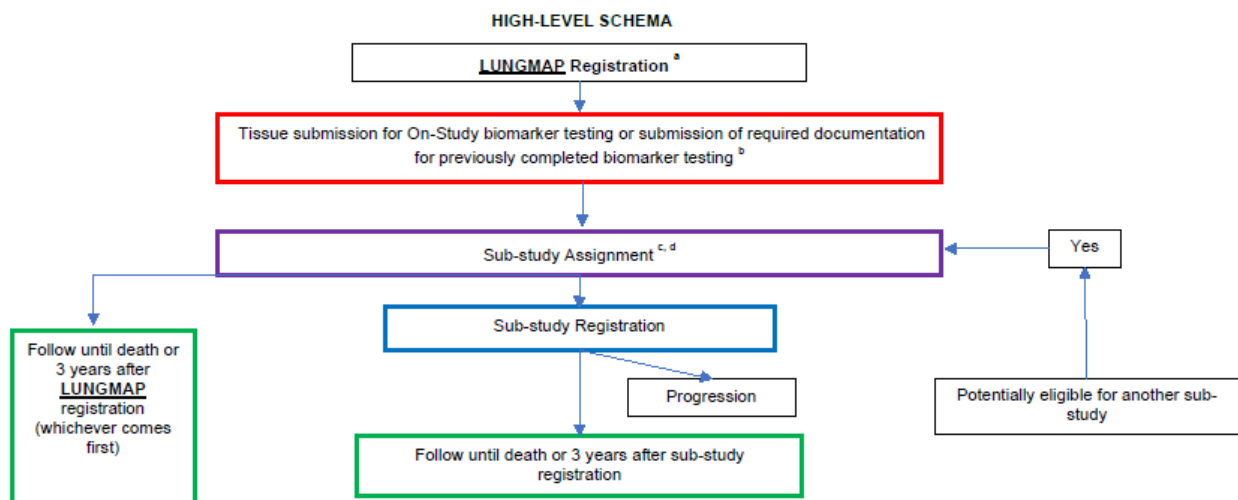
- The full biomarker report must be available to upload as source documentation in RAVE.
- The report must provide documentation of the following:
  - That the test was done on solid tumor tissue or blood (indicating which)
  - That the original report date on or after September 1, 2019.
- The participant must have consented to have these test results disclosed to SWOG Cancer Research Network (see Section 15.4).

b. For participants providing documentation of a previously completed test NOT on the list of approved labs, the test and associated documentation must meet ALL the following criteria:

- The full biomarker report must be available to upload as source documentation in RAVE.
- The test must have been performed within a laboratory with CLIA, ISO/IEC, CAP, or similar certification.
- The report must show that the test was done on solid tumor tissue or blood (indicating which).
- The full list of genes included in the test must either be documented on the report or documented separately.
- The report must show that the original report date was on or after September 1, 2019
- The report and associated documentation must have been submitted to LUNGMAPNGS@swog.org for review and an e-mail response must have been received documenting that the test is acceptable (see Section 15.4)
- The participant must have consented to have these test results disclosed to SWOG Cancer Research Network (see Section 15.4).

c. For participants with a previously completed NGS test based on blood only, the test must provide documentation of the presence of at least one of the alterations listed on the **LUNGMAP** Genomic Alterations Form.

If the report for blood-based NGS does not document the presence of at least one of these alterations, the participant is not eligible. To be eligible, the participant must either submit documentation of an approved tissue-based NGS test or submit tissue for on-study biomarker testing.



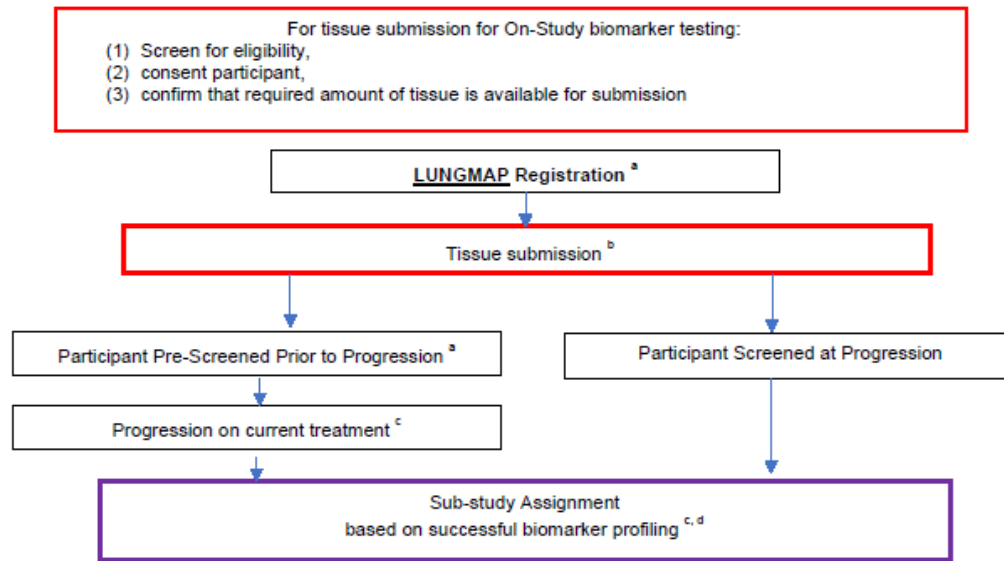
<sup>a</sup> Participants planning to have tissue submitted for on-study biomarker testing may enroll to be pre-screened prior to progression on current treatment or to be screened at progression. See [Section 5.1](#) for details on pre-screening. All other participants must enroll to be screened at progression.

<sup>b</sup> See [Section 5.4](#), [5.5](#), [5.6](#), [7.1](#), and [15.4](#) for details.

<sup>c</sup> Pre-screened participants must submit the **LUNGMAP** Notice of Progression to receive their sub-study assignment. See [Section 5.1](#), [7.1](#), [14.4d](#), and [18.1a](#) for more details.

<sup>d</sup> Sub-study assignments will be provided for participants meeting the criteria to be assigned to a biomarker-matched or non-match sub-study. Participants not meeting the criteria will be notified of lack of sub-study assignment. Notification of sub-study assignment will be sent by e-mail. See [Section 7.1](#) and [18.1a](#).

### ON-STUDY TISSUE TESTING SCHEMA



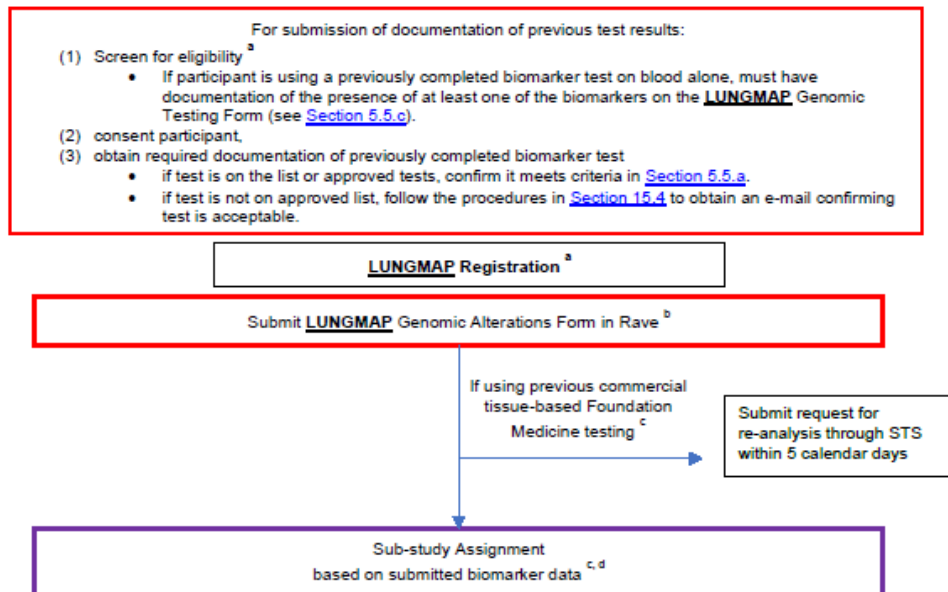
<sup>a</sup> Participants planning to have tissue submitted for on-study biomarker testing may enroll to be pre-screened prior to progression on current treatment or to be screened at progression. See [Section 5.1](#) for details on pre-screening.

<sup>b</sup> See [Section 5.1](#), [7.1](#), and [15.2](#) for details.

<sup>c</sup> Pre-screened participants must submit the [LUNGMAP](#) Notice of Progression to receive their sub-study assignment. See [Section 5.1](#), [7.1](#), [14.4d](#), and [18.1a](#) for more details.

<sup>d</sup> Sub-study assignments will be provided for participants meeting the criteria to be assigned to a biomarker-matched or non-match sub-study. Participants not meeting the criteria will be notified of sub-study assignment. Notification of sub-study assignment will be sent by e-mail. See [Section 7.1](#) and [18.1a](#).

### OUTSIDE TEST RESULTS SCHEMA



<sup>a</sup> Participants using previously completed test are only eligible to be screened at progression or treatment-naïve. See [Section 5.3](#) and [Section 5.4](#) for details.

<sup>b</sup> See [Section 14.4a](#), [15.2](#), and [15.3](#) for details.

<sup>c</sup> See [Section 7.0](#) for details.

<sup>d</sup> Sub-study assignment within 1 day of submission of [LUNGMAP](#) Genomic Alterations Form in Rave. Sub-study assignments will be provided for participants meeting the criteria to be assigned to a biomarker-matched or non-match sub-study. Participants not meeting the criteria will be notified of lack of sub-study assignment. Notification of sub-study assignment will be sent by e-mail. See [Section 7.1](#) and [18.1a](#).