LUNGMAP Master Protocol

Coordinating Group: SWOG

A Master Protocol to Evaluate Biomarker-Driven Therapies and Immunotherapies in Previously-Treated Non-Small Cell Lung Cancer (Lung-MAP Screening Study)

Participants:
SWOG, CTSU (Supported by Alliance, CCTG, ECOG-ACRIN, and NRG)

Date Activated:
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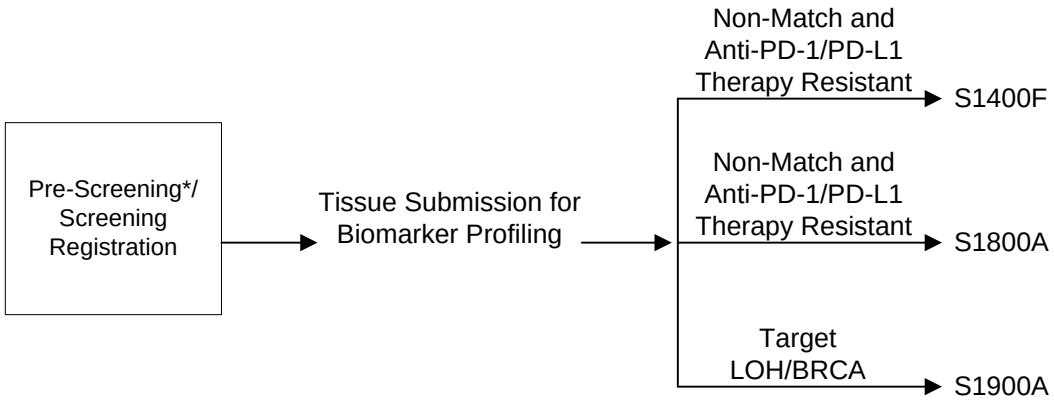
SCHEMA



*Patients must progress on current treatment to receive sub-study assignment.

Objectives

To test patient specimens to determine eligibility for participation in the biomarker-driven and non-matched sub-studies included within the Lung-MAP umbrella protocols.

To evaluate the screen success rate defined as the percentage of screened patients that register for a therapeutic sub-study.

To evaluate circulating tumor DNA (ctDNA) and compare to the FMI Foundation tissue molecular profiling results in patients who submit a new biopsy for screening.

To establish a tissue/blood repository.

Patient Population

LUNGMAP is an expansion on the previous umbrella protocol S1400. LUNGMAP allows all histologic types of non-small cell lung cancer (NSCLC).

Patients must have pathologically proven NSCLC confirmed by tumor biopsy and/or fine-needle aspiration. Disease must be Stage IV or recurrent. Patients must have adequate tumor tissue available (defined as at least 20% tumor cells and at least 0.2 mm^3 tumor size as confirmed by the treating institution's local pathologist). If archival tumor material is exhausted, then a new fresh tumor biopsy that is formalin-fixed and paraffin-embedded must be obtained. Patients must agree to have this tissue submitted to Foundation Medicine for common broad platform CLIA biomarker profiling, PD-L1 IHC, and c-MET IHC. Patients must not have EGFR sensitizing mutations, EGFR T790M mutations, ALK gene fusions, ROS1 gene rearrangements, or BRAF V600E mutations unless they have progressed following all standard of care targeted therapy.

Patients can either be screened upon progression on prior treatment or pre-screened prior to progression on current treatment. Patients screened at progression must have received at least one line of systemic therapy for any stage of disease and must have progressed during or following their most recent line of therapy. For patients whose prior systemic therapy was for Stage I-III disease only, progression on platinum-based chemotherapy must have occurred within one year from their last day of that therapy. For patients treated with consolidation anti-PD-1 or anti-PD-L1 therapy for Stage III disease, progression must have occurred within one year from the date of initiation 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 or anti-PD-1/PD-L1 therapy, alone or in combination. To be eligible for pre-screening, current treatment must be for Stage IV or recurrent disease and patient must have received at least one dose of the current regimen. Patients must have previously received or currently be receiving a platinum-based chemotherapy regimen or anti-PD-1/PD-L1 therapy, alone or in combination.

Patients must have a Zubrod performance status of 0-1 and be willing to provide prior smoking history.

Patients who need a fresh biopsy must also submit whole peripheral blood for ctDNA testing. Patients must agree to have any tissue that remains after testing retained for the use in sub-study Translational Medicine studies. Patients must also be offered participation in banking for future use of specimens.

Accrual Goals

This study is intended to be a long-term ongoing project to establish a National Clinical Trials Network (NCTN) mechanism for genomically screening large but homogeneous lung cancer populations and subsequently assigning and accruing simultaneously to multiple sub-studies. Each sub-study will have its own accrual goal. It is estimated that about 1,000 patients will be screened per year, with 40%-50% of patients registering to a sub-study.