

A lung cancer precision medicine trial

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Biomarker Profiling Based on Previous FoundationOne CDx Results: An FAQ

Earlier this year, LUNGMAP eligibility was expanded to allow reanalysis



FOUNDATIONONE®CDx

of results from a previous commercial FoundationOne CDx solid tumor test (reported September 1, 2019 or later) to be used for biomarker profiling instead of a tissue submission. This option can be easier for site coordinators and has the added benefit of not using tissue resources that are sometimes very limited. It can also open up the trial to patients who don't have archival tissue available and cannot undergo a biopsy.

The Lung-MAP FAQ document has been updated to include FAQs regarding the reanalysis of commercial FoundationOne CDx reports; please review it on the Required Lung-MAP Training page on the SWOG website.

Some additional Q&As compiled by the Lung-MAP data coordinators include:

- **Q:** Can results from a commercial FoundationOne CDx test done on a bone specimen be used for reanalysis on LUNGMAP?
- **A:** Yes, successful results from Foundation-One CDx (solid tissue test) done on a bone specimen, including a decalcified specimen, are acceptable for reanalysis. Please note that decalcified bone specimens cannot be submitted for on-study biomarker profiling per protocol.
- **Q:** Can results from a commercial FoundationOne CDx test done on a pleural fluid specimen or another cytology

specimen be used for reanalysis on LUNGMAP?

- **A:** Yes, successful results from FoundationOne CDx can be used for reanalysis as long as the solid tissue test was done on a cell block created from pleural fluid or another cytology specimen.
- **Q:** Can results from a FoundationOne Heme report be used if done on a solid tissue specimen?
- **A:** No, FoundationOne Heme results cannot be used for reanalysis and do not meet the LUNGMAP eligibility criterion.
- **Q:** If the FoundationOne CDx report lists the diagnosis as something other than NSCLC (for example, carcinoma of an unknown primary), will this be allowed?
- **A:** Potentially; please provide documentation for the change in diagnosis to Foundation Medicine at lung.map@foundationmedicine.com after the reanalysis request is submitted.

S1800D Approaches the Launch Pad; S1900F Coming Soon

Lung-MAP sub-study S1800D is in its final review stages and is expected to activate in the first quarter of 2022. It will test N-803 (ALT-803) plus pembrolizumab versus standard of care in patients with stage IV or recurrent NSCLC previously treated with anti-PD-1 or anti-PD-L1 therapy. Register now to attend an S1800D training webinar Thursday, January 13, 12-1 pm CST. And download the S1800D training slides from the Required Lung-MAP **Training** page.

S1900F is a study of carboplatin and pemetrexed with or without selpercatinib in patients with RET fusionpositive disease who have progressed on previous RET-directed therapy. It is expected to open by spring. Stay tuned!

LEARN MORE AT WWW.LUNG-MAP.ORG









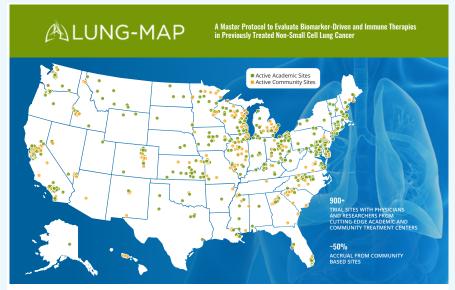


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Lung-MAP by the Numbers: **New Infographic Available!**

The Lung-MAP team has assembled a full-page infographic that provides a numerical overview of study progress.

You can download a full-size PDF you can print out for your team!



Nearly 30 Public and Private Collaborators and Supporters in Partnership since 2014

PARTNERING PRECISION MEDICINE DIAGNOSTIC COMPANIES AND LEADING PHARMACEUTICAL COMPANIES

INVESTIGATIONAL DRUGS OR DRUG COMBINATIONS TESTED

16 Initiated | 14 Completed

SUB-STUDIES CONDUCTED

AGENTS AGAINST SPECIFIC TUMOR MUTATIONS/GENETIC SIGNATURES TESTED IN NSCLC

MONTH AVERAGE SUB-STUDY STAND UP TIME FROM APPROVAL BY THE LUNG-MAP DRUG SELECTION COMMITTEE TO ACTIVATION

MONTH AVERAGE TIME TO TARGET ACCRUAL COMPLETION FOR ~80 PERSON STUDY, DRIVEN BY BIOMARKER PREVALENCE

SUPPORTING PATIENT ADVOCACY GROUPS

~4.000 | ~650 Per Year PATIENTS SCREENED

~2 500

PATIENTS ELIGIBLE FOR A TREATMENT IN A WELL-DESIGNED TRIAL

~1 000 | 150+ Per Year PATIENTS TREATED WITH CUTTING-EDGE THERAPIES

ALTERED GENES INTERROGATED IN EACH PATIENT'S TUMOR

24%

UNDERSERVED MINORITY PARTICIPANTS ENROLLED

ORGANIZATIONS, INCLUDING NCI AND FDA, WORKING TOGETHER TO CONDUCT AND OVERSEE THE STUDY

ANNOTATED SPECIMENS IN A TISSUE BANK TO ALLOW DEEPER SCIENTIFIC STUDIES TO INFLUENCE FUTURE TRIALS

PUBLICATIONS AND ABSTRACTS

Additional Benefits of Lung-MAP

SHARED COSTS AND RISKS OF TESTING THERAPEUTICS FOR COMPANIES

THERAPEUTICS FOR COMPANIES
FOSTERING DRUG COMBINATION
COLLABORATIONS BETWEEN COMPANIES
ACCELERATED TIMETRAMES FOR
EVALUATION OF TREATMENT EFFICACY DUE
TO THE LARGE NETWORK STRONG SUPPORT FROM THE FDA WITH ABILITY FOR STUDIES TO HAVE REGULATORY INTENT

Highly Motivated Expert Partners for Trial Conduct













The new Lung-MAP protocol has logged:

2,267 screening registrations 1,033 sub-study assignments **319** sub-study registrations

TOP-ACCRUING SITES*

1.	UPMC Hillman Cancer Cent	er
	Pittsburgh, PA	138

2. UNM Comprehensive Cancer Center Albuquerque, NM 44

3. Wilmot Cancer Institute Rochester, NY

Canton, OH

4. Mercy Medical Center 38

43

5. Missouri Baptist Medical Center St. Louis, MO

6. Roswell Park Comprehensive Cancer Center Buffalo, NY 27

7. Markey Cancer Center Lexington, KY

25

25

7. Edwards Comprehensive Cancer Center Huntington, WV 25

7. Baystate Medical Center Springfield, MA

8. Stephenson Cancer Center 24

Oklahoma City, OK 8. Good Samaritan Hospital Cincinnati, OH

24

9. Virginia Cancer Institute Richmond, VA

23

9. Eastern Maine Medical Center Cancer Care Brewer, ME 23

9. VA Connecticut Healthcare System — West Haven West Haven, CT

23 23

9. Essentia Health Duluth, MN

10. Northside Hospital Cancer Institute Atlanta, GA

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*As of December 12, 2021

CONTACT US

General Medical Questions <u>LUNGMAP@swog.org</u>

Protocol & Regulatory Questions lgildner@swog.org or jbeeler@swog.org

Central Monitoring Questions centralmonitorquestion@crab.org

Eligibility & Data Submission Questions LUNGMAPQuestion@crab.org

Quality Assurance Auditing Questions gamail@swog.org

Funding Questions funding@swog.org

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