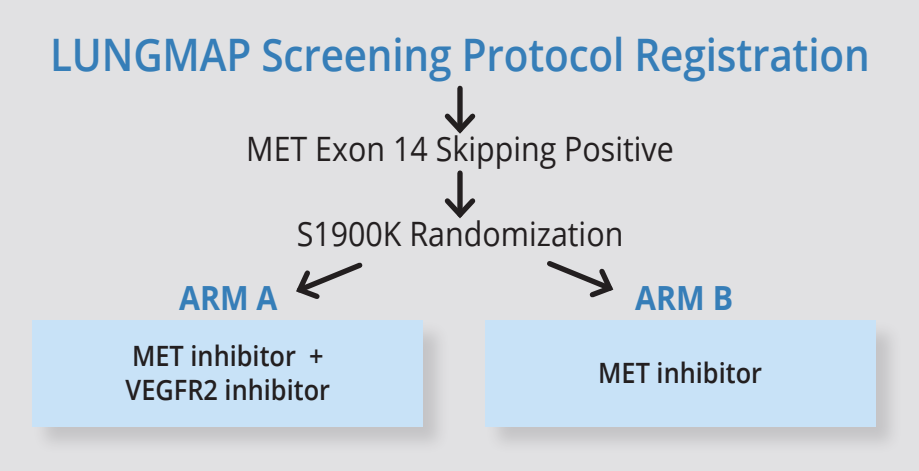
LUNG-MAP
A lung cancer precision medicine trial
VOLUME 24 | FALL 2023 NEWSLETTER WWW.LUNG-MAP.ORG

S1900K and S1900J Soon to Launch

Lung-MAP's next two biomarker-driven sub-studies are in the final stages of development and contracting and will be activated soon.

S1900K: MET exon 14-skipping gene change

S1900K is likely to be the first to open. It will enroll patients whose tumors exhibit a MET exon 14-skipping gene change and who have not previously received a MET inhibitor.



The study team hypothesizes that resistance to a MET inhibitor in these patients is driven by VEGFR2 signaling, and the trial randomizes patients to MET inhibitor treatment with or without a VEGFR2 inhibitor.

All patients must be registered through the LUNGMAP protocol, but confirmation of MET exon 14-skipping status may be documented by a local CLIA-certified laboratory testing either tissue or blood.

S1900K is being chaired by ECOG-ACRIN's Paul Paik, MD, with Xiuning Le, MD, as co-chair. The enrollment goal is 56 patients.

S1900J: MET amplification-positive NSCLC

Expected to open early in the new year, S1900J will enroll patients whose tumors exhibit MET amplification. The sub-study will enroll squamous and non-squamous cohorts, with all patients treated with an investigational bispecific antibody that targets both EGFR and MET signaling.

S1900J is being chaired by SWOG's Christian Rolfo, MD, PhD, MBA, with Shirish Gadgeel, MD, as co-chair. The enrollment goal is 88 patients.

We encourage you to open *all* new sub-studies as soon as possible after activation rather than to pick and choose select sub-studies to open.

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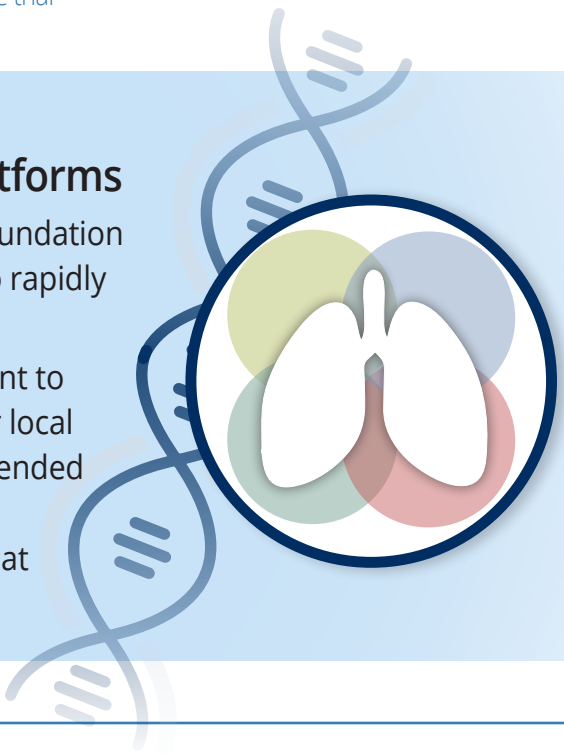
COMING SOON:

Lung-MAP Screening with a Range of NGS Platforms

Many of you have told us that being required to use the Foundation Medicine screening assay has become a significant barrier to rapidly enrolling patients to Lung-MAP.

So, the study team has been hard at work on an amendment to the LUNGMAP protocol that provides options for using other local or commercial next-generation screening platforms. The amended protocol should simplify screening and make the trial more inclusive. We'll send you updates in the coming months as that change approaches activation!



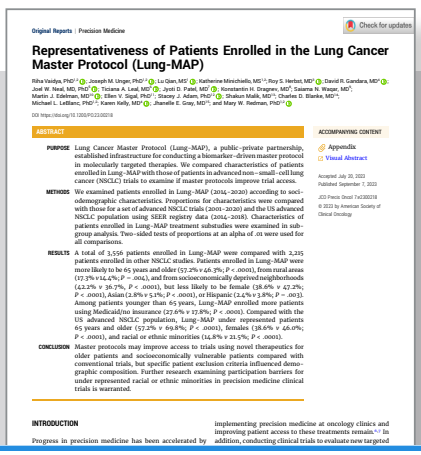
Three Papers Address Lung-MAP's Promise and Uniqueness

An analysis of the representativeness of the Lung-MAP patient population was published in September in the journal *JCO Precision Oncology*. Initial results from this analysis were presented at the 2022 ASCO annual meeting by lead author Riha Vaidya, PhD.

It found that, compared to conventional SWOG trials in advanced NSCLC, the Lung-MAP approach increased access for older patients, patients from rural areas, patients from areas with greater socioeconomic challenges, and patients who have Medicaid or who have no insurance.

The journal ran an editorial in conjunction with the Vaidya paper, titled "Clinical Trial Diversity: A Bend in the Arc Toward Justice." It argued that the Lung-MAP approach – particularly the public–private collaboration underlying Lung-MAP – may suggest a route to making industry-funded clinical trials more representative and accessible.

A perspective piece just out in *Clinical Cancer Research*, written by Roy Herbst, MD, PhD; Charles Blanke, MD; and Ellen Sigal, PhD, explores this unique public-private partnership as a key factor in Lung-MAP's success.

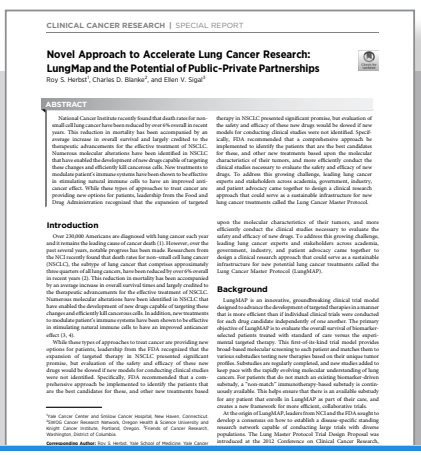


Original Reports | Precision Medicine

Representativeness of Patients Enrolled in the Lung Cancer Master Protocol (Lung-MAP)

Editorials

Clinical Trial Diversity: A Bend in the Arc Toward Justice



CLINICAL CANCER RESEARCH | SPECIAL REPORT

Novel Approach to Accelerate Lung Cancer Research: LungMap and the Potential of Public-Private Partnerships

Lung-MAP Advocate Webinar Now Online

In August, the Lung-MAP team convened an online forum to update patient advocacy partners on the master protocol's progress, sub-studies, and plans.

The session included a presentation by Dr. Jay Nayak, of AnMed Health Cancer Center, on how a small community treatment center has succeeded in bringing Lung-MAP to its patients.

A panel discussion featured three lung cancer advocacy organization leaders:

- Terri Conneran, founder and director of KRAS Kickers
- Ivy Elkins, cofounder of EGFR Resisters
- Dr. Upal Basu Roy, executive director of research for LUNGevity

Here are a few of the points the panelists highlighted:

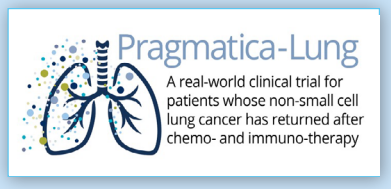
- Lung-MAP's value proposition is that it has something for everyone based on the molecular profile of their tumor. Even assignment to the "non-match" sub-study is precision medicine driven [view].
- Patients struggle with the complexity of informed consents and need an "executive summary" for a trial, answering their key questions using simple language. Ideally, this should be available in a variety of media (text, visual, video, etc.) [view].
- Patients and caregivers should also have a phone number they can rely on to get answers [view]. *(The NCI's 1-800-4-CANCER is one such resource.)*
- Patients benefit from being able to ask questions of multiple experts with multiple perspectives: nurse navigator, oncologist, primary care physician, etc. [view].
- Patients need time to decide to participate, and 48 hours is not enough. Give them at least 5 – 7 days [view].
- A strength of Lung-MAP is that it has evolved with the science and the needs of patients. The trial should continue to be flexible and nimble [view].
- The trial should involve patient advocates as true partners from the earliest stages of study development [view].

Terri Conneran of KRAS Kickers delivered the panel's final closing thought: "The research y'all are working on today is going to be saving our lives tomorrow, so just keep on doing what you've gotta do, and let's get it there" [view].

Questions about Conducting Lung-MAP? Updated FAQs Now Available

The list of Frequently Asked Questions for the LUNGMAP screening protocol was updated in September.

An FAQ for S1900G has also been posted recently and reviews screening details specific to this sub-study. S1900G requires testing for MET amplification *after* disease progression on osimertinib, but it allows this additional testing to be done by certain assays other than the Foundation Medicine assay.



S2302 A Great Option for Your Non-Match Patients

If you have Lung-MAP patients ready for assignment to a non-match sub-study, consider enrolling them to the S2302 Pragmatica-Lung trial. It's a streamlined study that's easy to open, conduct, and enroll to. No additional specimens required!

A new Lung-MAP non-match sub-study is in development but is not expected to be ready to launch until well into 2024.

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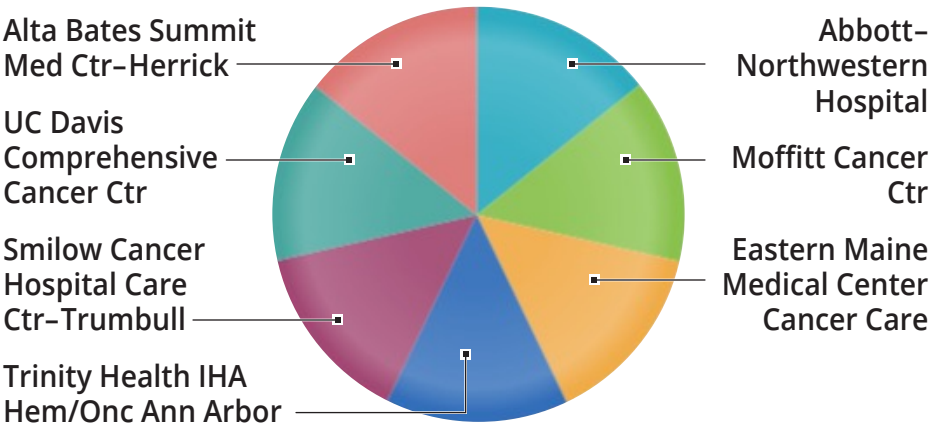
S1900E and S1900G Accruing Well!

Lung-MAP's two open biomarker sub-studies are strong performers.

S1900E is nearing its accrual targets in all three cohorts. Protocol revision #5 was posted in September. The primary change is the inclusion of new information about the analysis of circulating tumor DNA (ctDNA).

S1900G has already enrolled seven patients (at seven sites!). Protocol revision #1 was posted recently and clarifies details about the trial's safety run-in.

S1900G PATIENT ACCRUAL BY SITE, NOV 15, 2023



Total enrollment: 7 patients

TOP-ACCRUING SITES TO LUNGMAP*

1. UPMC Hillman Cancer Center	Pittsburgh, PA	**154**
2. Edwards Comprehensive Cancer Center	Huntington, WV	**60**
3. UNM Comprehensive Cancer Center	Albuquerque, NM	**59**
4. Wilmot Cancer Institute Univ of Rochester	Rochester, NY	**58**
5. Mercy Medical Center	Canton, OH	**49**
6. Missouri Baptist Medical Center	St. Louis, MO	**47**
7. Dartmouth Hitchcock Med Ctr/Dartmouth Cancer Ctr	Lebanon, NH	**37**
7. VA Connecticut Healthcare System – West Haven	West Haven, CT	**37**
8. Baystate Medical Center	Springfield, MA	**36**
8. UC Davis Comprehensive Cancer Center	Davis, CA	**36**
9. Palo Alto Medical Foundation – Sunnyvale	Sunnyvale, CA	**35**
10. AnMed Health Cancer Center	Anderson, SC	**34**

* As of November 18, 2023

AS OF NOVEMBER 18, 2023, THE LUNGMAP SCREENING PROTOCOL HAS LOGGED:

3,222
screening registrations

1,699
sub-study assignments

469
sub-study registrations

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