



LUNG-MAP

A lung cancer precision medicine trial

S1900K and S1900J Soon to Launch

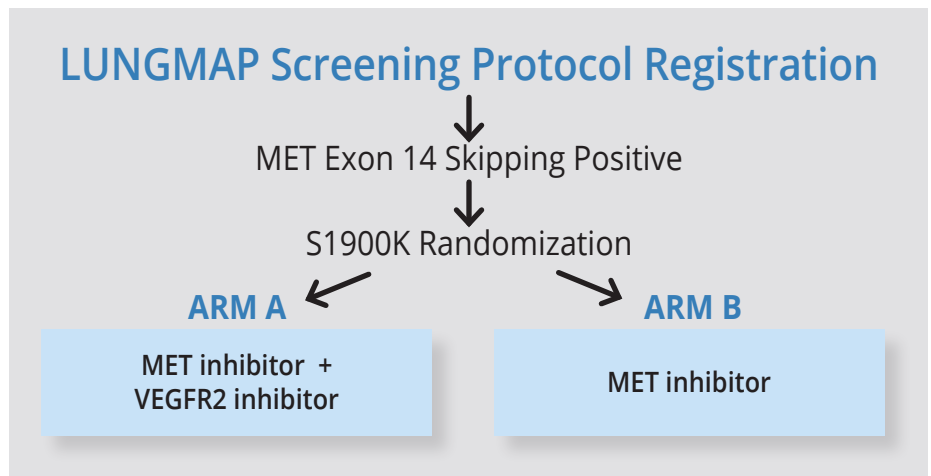
Lung-MAP's next two biomarker-driven sub-studies are in the final stages of development and contracting and will be activated soon.

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.

LEARN MORE AT WWW.LUNG-MAP.ORG



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 Rihya 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)

Rihya Vaidya, PhD¹, Joseph M. D'Amico, PhD², Li-Qun Chen, MD³, Katherine M. Mikhalek, MD⁴, Roy S. Herbst, MD⁵, David R. Gandek, MD⁶, Jun-Ri Hong, MD⁷, E. Travis A. Scharf, MD⁸, Elizabeth H. Striegel, MD⁹, James H. Vespa, MD¹⁰, Mark A. Eckman, MD¹¹, Ellen V. Sigal, PhD¹², Stacy J. Adams, PhD¹³, Steven M. Liaw, MD¹⁴, Charles D. Blanke, MD¹⁵, Michael J. Lubitz, PhD¹⁶, Karen Kelly, MD¹⁷, Jennifer C. Gray, MD¹⁸, and Roy S. Herbst, MD¹⁹

DOI: 10.1200/JCO.2022.41.18.3582

ABSTRACT

PURPOSE Lung Cancer Master Protocol (Lung-MAP), a public-private partnership, established infrastructure for conducting a biomarker-driven master protocol in molecularly targeted therapies. We compared characteristics of patients enrolled in Lung-MAP with those of patients in advanced non-small-cell lung cancer (NSCLC) trials to examine if master protocols improve trial access.

METHODS We examined patients enrolled in Lung-MAP (2014-2020) according to sociodemographic characteristics. Proportions for characteristics were compared with those for a set of advanced NSCLC trials (2010-2020) and the US advanced NSCLC population using SEER registry data (2014-2018). Characteristics of patients enrolled in Lung-MAP treatment subtypes were examined in subgroup analysis. Two-sided tests of proportions at an alpha of .05 were used for all comparisons.

RESULTS A total of 3,556 patients enrolled in Lung-MAP were compared with 2,125 patients enrolled in other NSCLC studies. Patients enrolled in Lung-MAP were more likely to be 65 years and older (52.2% v 48.2%, $P < .0001$), from rural areas (12.3% v 10.2%, $P = .0002$), and from socioeconomically deprived neighborhoods (42.3% v 38.2%, $P < .0001$), but less likely to be female (34.6% v 47.2%, $P < .0001$), Asian (2.8% v 5.7%, $P < .0001$), or Hispanic (2.5% v 3.8%, $P = .0003$). Among patients younger than 65 years, Lung-MAP enrolled more patients using Medicare insurance (25.4% v 27.9%, $P < .0001$). Compared with the US advanced NSCLC population, Lung-MAP enrolled more patients 65 years and older (52.2% v 49.8%, $P < .0001$), female (34.6% v 48.4%, $P < .0001$), and racial or ethnic minorities (14.8% v 15.7%, $P < .0001$).

CONCLUSION Master protocols may improve access to trials using novel therapeutics for older patients and socioeconomically vulnerable patients compared with conventional trials, but specific patient exclusion criteria influenced demographic composition. Further research examining participation barriers for under-represented racial or ethnic minorities in precision medicine clinical trials is warranted.

INTRODUCTION Implementing precision medicine at oncology clinics and improving patient access to these treatments remain¹⁻³ in progress in precision medicine has been accelerated by addition, conducting clinical trials to evaluate new targeted

Editorials

Clinical Trial Diversity: A Bend in the Arc Toward Justice

Susan H. Tamborini, MD¹ and Jennifer E. Miller, PhD²

DOI: 10.1200/JCO.2022.41.18.3583

ABSTRACT

It is well-established that women, older adults, and racial and ethnic minorities, among other groups, are often under-represented in oncology research. A stark recent example includes the Lilly and Inovio Biotech's submission of a new drug, mirvetuximab, for US Food and Drug Administration (FDA) approval to treat non-small-cell lung cancer (NSCLC) on the basis of a pivotal trial conducted in China, enrolling significantly younger participants than US patients with NSCLC, zero black, or Hispanic-identifying patients and far more men than women. While this may be an outlier case in some ways, and the product was not approved by the FDA, the FDA has approved many other products on the basis of unrepresentative trials. For FDA drug and biologic approval and real-world evidence to be equitable, there needs to be that inclusion of women, older adults, and ethnic, racial, and other under-represented groups (URGs) in clinical trials. In this article that accompanies this editorial, Representativeness of Patients Enrolled in the Lung Cancer Master Protocol (Lung-MAP), Vaidya et al¹ demonstrate a way forward to accomplish this.

Health equity involves a fair opportunity for everyone to achieve their highest level of health, which is jeopardized by systemic underinclusion of population groups in clinical trials and data sets supporting biomedical research.² Furthermore, clinical trial diversity may be vital for the test and uptake of medicines. A recent study found that racially and ethnically under-represented patients, and their clinicians, are more likely to treat and use new medical products when approved on the basis of studies enrolling a diverse population.³

In 1993, the National Institutes of Health Revitalization Act was enacted mandating inclusion of women and ethnic minorities into National Institutes of Health (NIH)-supported clinical trials. Ten years later, in 2003, the Committee on Understanding and Eliminating Racial and Ethnic Disparities in Health Care, National of Medicine, issued a report on shaping the future for health. The report quantified the differences in health care in USA, sources of differences, and recommendations to eliminate them, including reducing disparities in trial enrollment.

Today, 30 years after the 1993 Revitalization Act, clinical trial diversity remains a challenge. Chen et al⁴ reviewed the status of clinical trial access for NIH-funded trials, finding that the proportion of racial and ethnic minorities participating in cancer trials from 1993 to 2013 was persistently lower than the proportion of minorities in the US population, despite often being disproportionately burdened by many types of cancer.⁵ Multiple guidance documents have been published by the FDA on enhancing URGs in clinical trial enrollment including its 2006 guidance on the importance of broadening eligibility criteria and adopting more inclusive enrollment practices.⁶⁻¹⁰

While studies suggest that NIH-funded trials have improved enrollment of URGs, industry sponsors' most pivotal trials, supporting FDA approval of novel oncology products.

In 2016, Ramamoorthy et al¹¹ reviewed enrollment of demographic subgroups in clinical trials,

CLINICAL CANCER RESEARCH | SPECIAL REPORT

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

Roy S. Herbst¹, Charles D. Blanke², and Ellen V. Sigal³

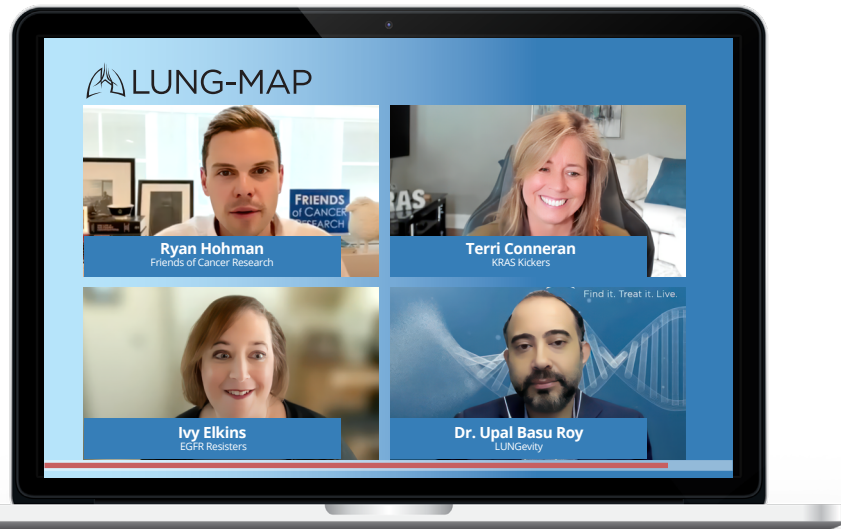
DOI: 10.1200/JCO.2022.41.18.3584

ABSTRACT

Novel cancer therapies recently found that death rates for non-small-cell lung cancer have been reduced by over 50% in recent years. The challenge is generally how best to accelerate the development of these therapies. The primary challenge is to ensure that the therapies are available to all patients who need them. The Lung Cancer Master Protocol (Lung-MAP) is a novel approach to accelerating the development of these therapies. Lung-MAP is a public-private partnership between the National Cancer Institute (NCI) and the Lung Cancer Research Consortium (LCRC). Lung-MAP is a master protocol that allows for the simultaneous testing of multiple therapies in a single trial. This approach allows for the rapid testing of multiple therapies and the identification of promising therapies. Lung-MAP is a novel approach to accelerating the development of these therapies. Lung-MAP is a public-private partnership between the National Cancer Institute (NCI) and the Lung Cancer Research Consortium (LCRC). Lung-MAP is a master protocol that allows for the simultaneous testing of multiple therapies in a single trial. This approach allows for the rapid testing of multiple therapies and the identification of promising therapies.

Introduction Over 230,000 Americans are diagnosed with lung cancer each year. Lung cancer is the leading cause of cancer death in the United States. The primary challenge is to ensure that the therapies are available to all patients who need them. The Lung Cancer Master Protocol (Lung-MAP) is a novel approach to accelerating the development of these therapies. Lung-MAP is a public-private partnership between the National Cancer Institute (NCI) and the Lung Cancer Research Consortium (LCRC). Lung-MAP is a master protocol that allows for the simultaneous testing of multiple therapies in a single trial. This approach allows for the rapid testing of multiple therapies and the identification of promising therapies.

Background LungMAP is an innovative, groundbreaking clinical trial model designed to accelerate the development of targeted therapies to treat lung cancer. The primary challenge is to ensure that the therapies are available to all patients who need them. The Lung Cancer Master Protocol (Lung-MAP) is a novel approach to accelerating the development of these therapies. Lung-MAP is a public-private partnership between the National Cancer Institute (NCI) and the Lung Cancer Research Consortium (LCRC). Lung-MAP is a master protocol that allows for the simultaneous testing of multiple therapies in a single trial. This approach allows for the rapid testing of multiple therapies and the identification of promising therapies.

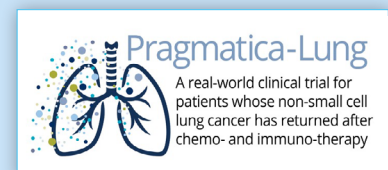


Questions about Conducting Lung-MAP? Updated FAQs Now Available

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 re-views 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.

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 LUNGevery

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" [\[view\]](#).

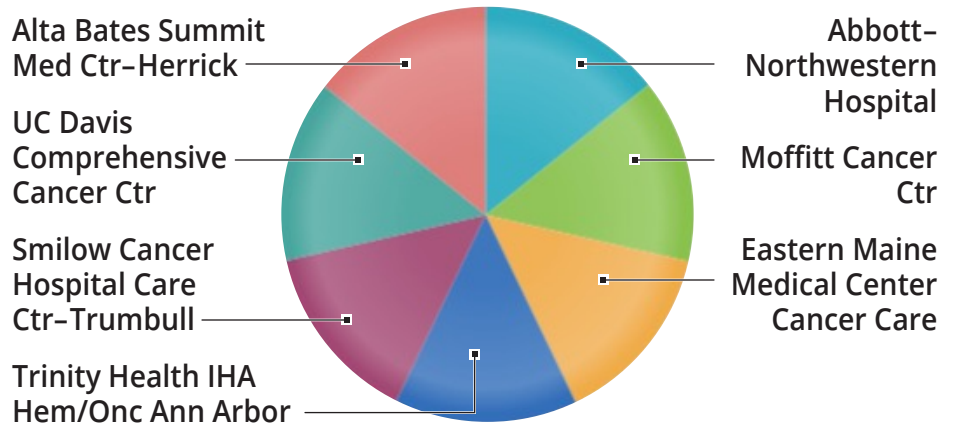
S1900E and S1900G Accruing Well!

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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