# LUNG-MAP Turns 10

## *Our Partnerships, Achievements, and Lessons Learned*

*"Lung-MAP is an umbrella master screening protocol whose sub-studies operate as a registration intent studies for both targeted, single agents and immunotherapy combinations in patients with IO-refractory non-small cell lung cancer of all histologies."*


**Roy S. Herbst MD, PhD**

**Lung Map PI Emeritus and Senior Advisor**
Ensign Professor of Medicine
Professor of Pharmacology
Deputy Director, Yale Cancer Center
Assistant Dean for Translational research
Yale School of Medicine


**October 17, 2023**

NCI National Clinical Trials Network | NCI Community Oncology Research Program

LUNG-MAP

SWOG CANCER RESEARCH NETWORK

YaleNewHavenHealth Smilow Cancer Hospital | Yale CANCER CENTER A Comprehensive Cancer Center Designated by the National Cancer Institute

Yale SCHOOL OF MEDICINE

# Disclosures: Roy S. Herbst, MD, PhD

- Consulting: AstraZeneca; Bolt Biotherapeutics; Bristol-Myers Squibb ; Candel Therapeutics, Inc.; Checkpoint Therapeutics; Cybrexa Therapeutics ; DynamiCure Biotechnology, LLC; eFFECTOR Therapeutics, Inc.; Eli Lilly and Company; EMD Serono; Genentech; Gilead; HiberCell, Inc., ; I-Mab Biopharma; Immune-Onc Therapeutics, Inc.; Immunocore; Janssen; Johnson and Johnson; Loxo Oncology; Mirati Therapeutics; NextCure; Novartis; Ocean Biomedical, Inc. ; Oncocyte Corp; Oncternal Therapeutics; Pfizer; Regeneron Pharmaceuticals; Revelar Biotherapeutics, Inc; Ribbon Therapeutics; Roche; Sanofi; WindMIL Therapeutics; Xencor, Inc
- Research Support: AstraZeneca; Eli Lilly and Company; Genentech/Roche; Merck and Company
- Board Member (non-executive/ independent): Immunocore; Junshi Pharmaceuticals

# Plan for the Talk

1. The Birth of Lung-MAP

2. Top Ten: Partnerships, Achievements, and Lessons Learned

3. Pragmatic thoughts for the Future

# Plan For the Talk

1. The Birth of Lung-MAP

2. Top Ten: Partnerships, Achievements, and Lessons Learned

3. Thoughts for the Future

# The Genesis of Lung-MAP

**October 2011 –** Creativity Inspiration motivated by TCGA and Battle trials at the SWOG Group Meeting

**February 2012 –** NCI TMSC, FDA, Leading Academicians, Clinicians, Industry, Government representatives

**November 2012 –** Lung Master Protocol Trial Design Proposal hosted by Friends of Cancer Research

**March 2013 –** Development of the Lung Master Protocol

**June 2014 –** Lung-MAP trial launched

- **Public-Private Partnerships - SWOG IND Sponsor**
- **Primary Objective**
  - Overall survival of biomarker-selected patients treated with standard of care (SoC) versus the experimental targeted therapy
- **Drugs and Biomarkers**
  - Steering Committee to evaluate each applicant
- **Study Design**
  - Phase II/III in patients with advanced squamous cell carcinoma as the un-met need
  - Foundation Medicine as the central lab for biomarker testing
  - Targeted treatment based on biomarker results

L-R: M. Redman, J. Abrams, V. Miller, A. Ashby,
V. Papadimitrakopoulou, D. Gandara, J. Woodcock, R. Herbst, J. Allen

NCI: National Cancer Institute;
TMSC: Thoracic Malignancies Steering Committee
TCGA: The Cancer Genome Atlas

SPECIAL ARTICLE

OPEN

Consensus Report of a Joint NCI Thoracic Malignancies Steering Committee: FDA Workshop on Strategies for Integrating Biomarkers into Clinical Development of New Therapies for Lung Cancer Leading to the Inception of "Master Protocols" in Lung Cancer

*Shakun M. Malik, MD,* Richard Pazdur, MD,† Jeffrey S. Abrams, MD,* Mark A. Socinski, MD,‡ William T. Sause, MD,§ David H. Harpole Jr., MD,‖ John J. Welch, MD, PhD,* Edward L. Korn, PhD,¶ Claudio Dansky Ullmann, MD,* and Fred R. Hirsch, MD PhD#*

(*J Thorac Oncol.* 2014;9: 1443–1448)

# Design of a Disease-Specific Master Protocol

2012 Friends of Cancer Research / Brookings Institution
Conference on Clinical Cancer Research


**ISSUE BRIEF**

**Conference on Clinical Cancer Research**

***November 2012***

## Design of a Disease-Specific Master Protocol

*Roy Herbst*, Chief of Medical Oncology, Yale Cancer Center
*Eric Rubin*, Vice President, Clinical Research Oncology, Merck
*Lisa LaVange*, Director, Office of Biostatistics, CDER, FDA
*Jeffrey Abrams*, Associate Director, Cancer Therapy Evaluation Program, NCI
*David Wholley*, Director, The Biomarkers Consortium, FNIH
*Karen Arscott*, Patient Advocate, Lung Cancer Alliance
*Shakuntala Malik*, Medical Officer, FDA

**Introduction**

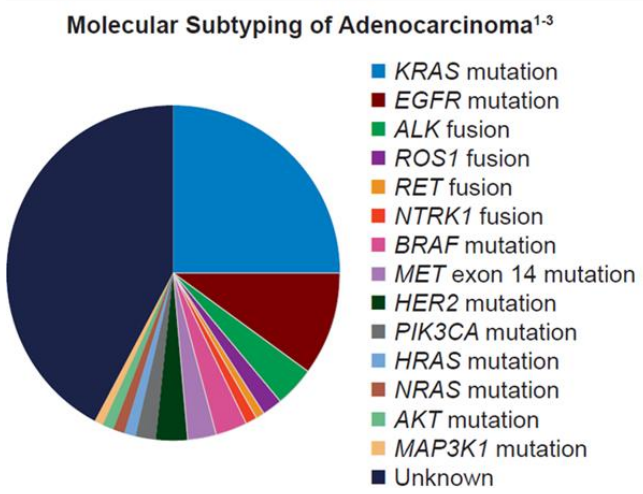
Despite several impressive therapeutic advances in recent years, cancer remains the second-leading cause of death in the United States, and effective new therapies are still desperately needed. Developing a potential therapy from the initial discovery stage through clinical testing and regulatory review is a complicated, expensive, and often inefficient process that can take up to 15 years. Included among the many challenges of drug development are the difficulties in recruiting cancer patients to clinical trials, the extensive bureaucratic processes required to initiate any clinical trial, and lengthy regulatory review. Modernizing this process with innovative approaches and new clinical trial designs is of high importance.

FRIENDS of CANCER RESEARCH

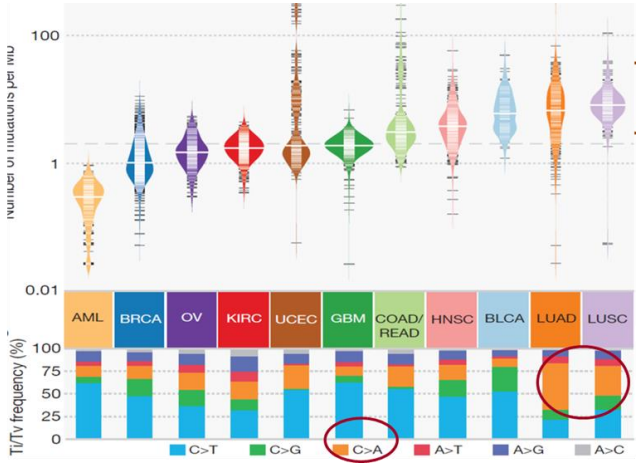
http://www.focr.org/events/design-lung-cancer-master-protocol

# Advanced NSCLC as an Ideal Tumor Type for a Master Protocol

**Genomically complex**




**Immunologically Well Suited**



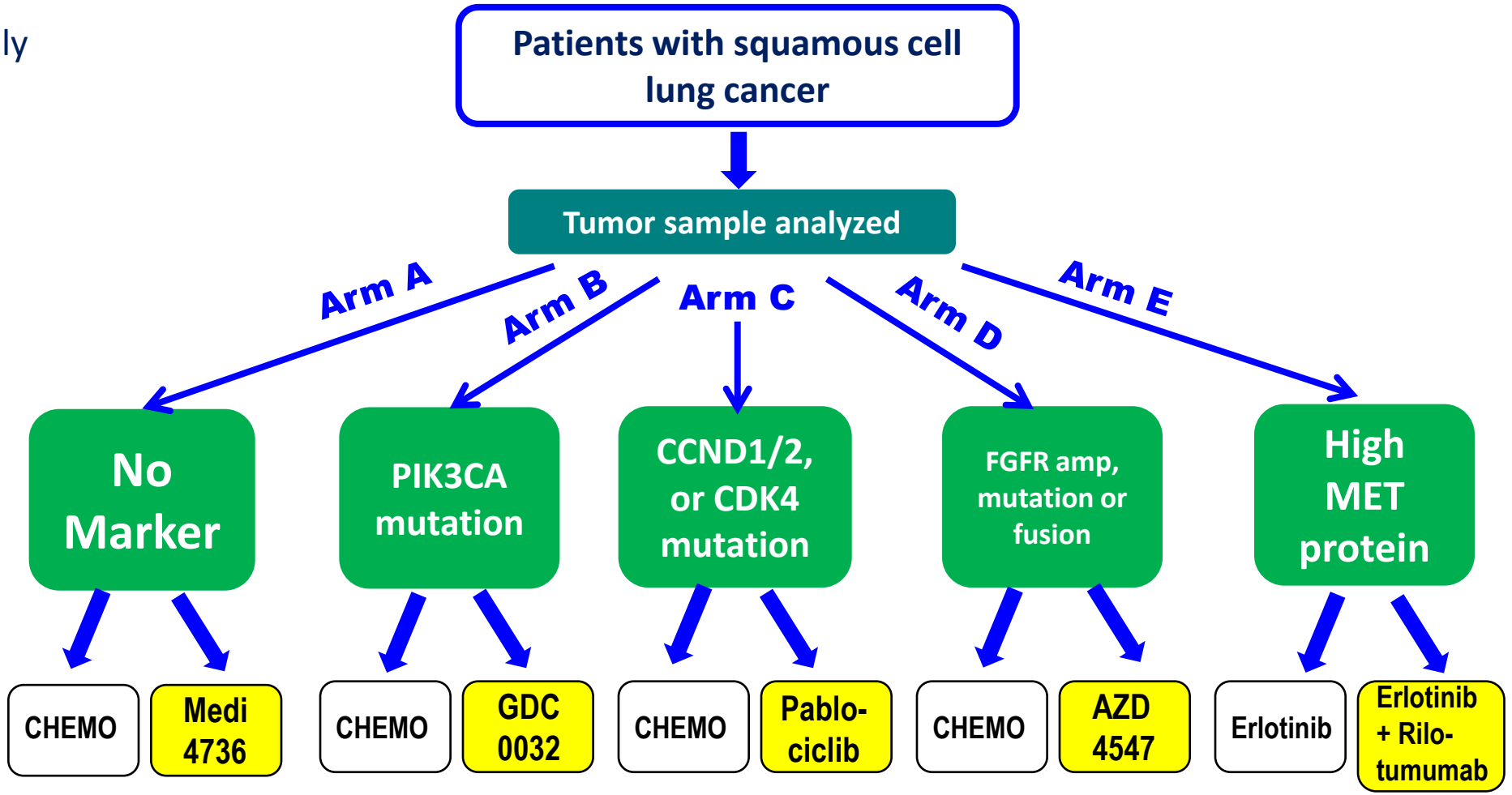

## Goals of the Lung MAP Master Protocol:

- Test new anti-cancer therapies in uncommon-rare genotypes of NSCLC?
- Test new anti-cancer therapies in NSCLC patients refractory to IO
- Apply broad-based molecular screening (NGS) in the clinic
- Achieve an acceptable turn-around time for molecular testing in the clinic (<2 weeks)
- Expedite the clinical trials process (through a public-private partnership)
- Bring Lung MAP to NCTN community sites nationwide (“bring the trials to the patient”)
- Create “New Science” from Lung MAP resources

# The first open sub-studies

**Open June 2014**

Squamous only
2nd line
SWOG




AstraZeneca
Genentech BIO ONCOLOGY
Pfizer
MedImmune
AMGEN

# Recognized by 21st Century Cures: Modernizing Clinical Trials

## Recommendations to the committee:

- Biomarkers: Increase rate of per patient reimbursement to support and incentivize studies that evaluate biomarkers
- Diagnostics: Develop a framework of policies to govern advanced diagnostics
- Partnerships: Examine incentive structures and processes to help establish more multi-stakeholder partnerships to accelerate the clinical trials process
- Resources: Sustained funding for NIH and FDA and a diminution of the constraints on education, travel and paperwork that complicate the process

# Plan For the Talk

1. The Birth of Lung-MAP

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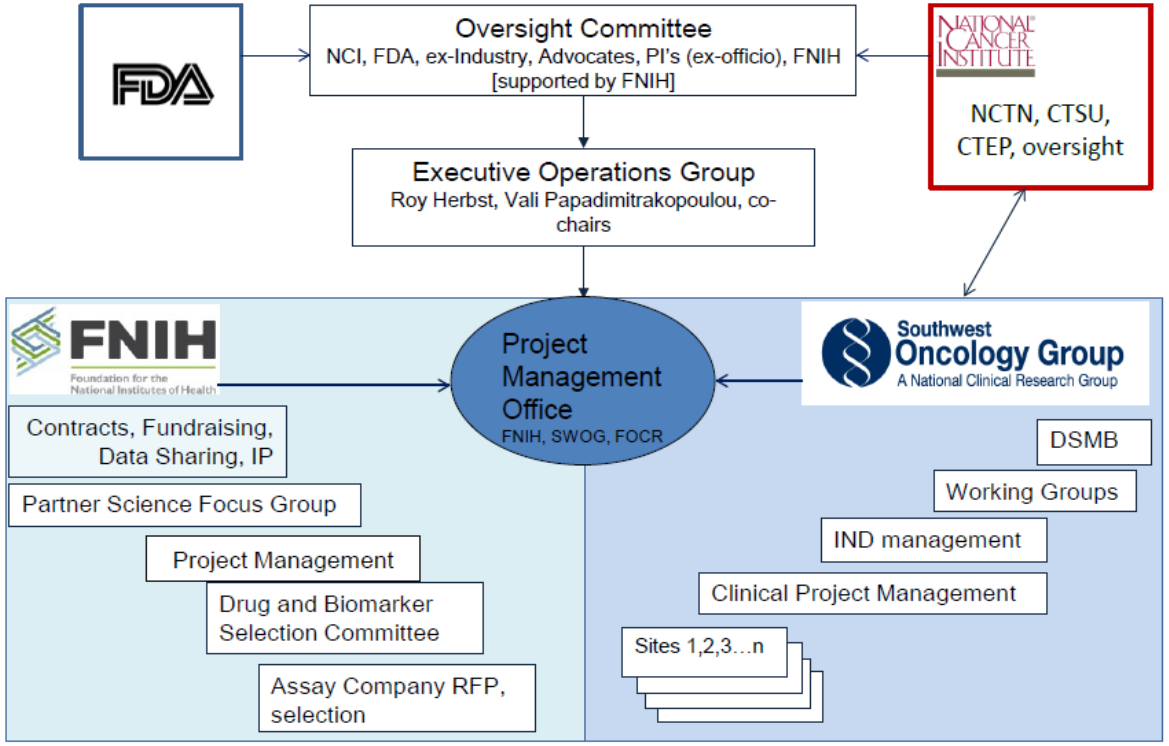
3. Thoughts for the Future

# #1 It takes a Village: Teamwork breeds success




FOUNDATION MEDICINE

AstraZeneca

Bristol Myers Squibb

abbvie

Pfizer

Genentech BIO ONCOLOGY

AMGEN

Lilly

MedImmune

MERCK

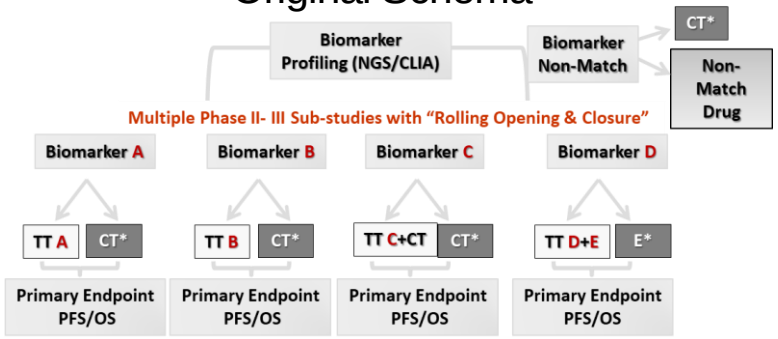
CLOVIS ONCOLOGY

LOXO ONCOLOGY
Wholly owned subsidiary of Eli Lilly and Company

ImmunityBio

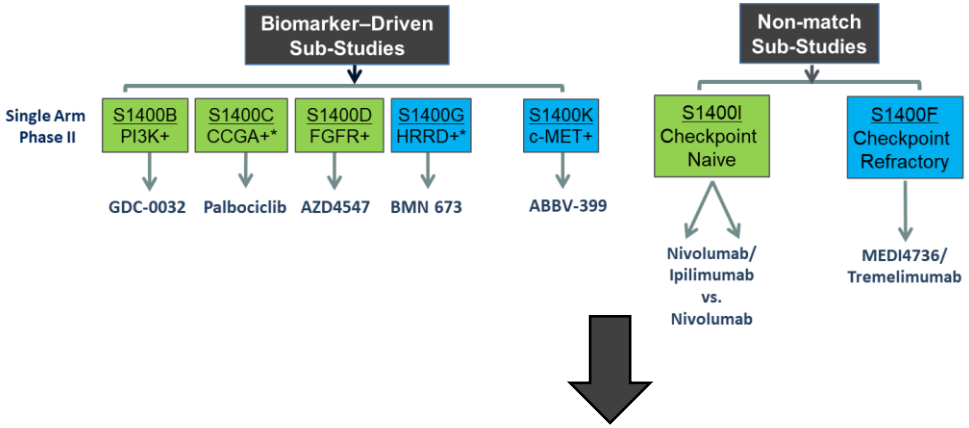
# #2 Evolve with the treatment landscape

## Original Schema

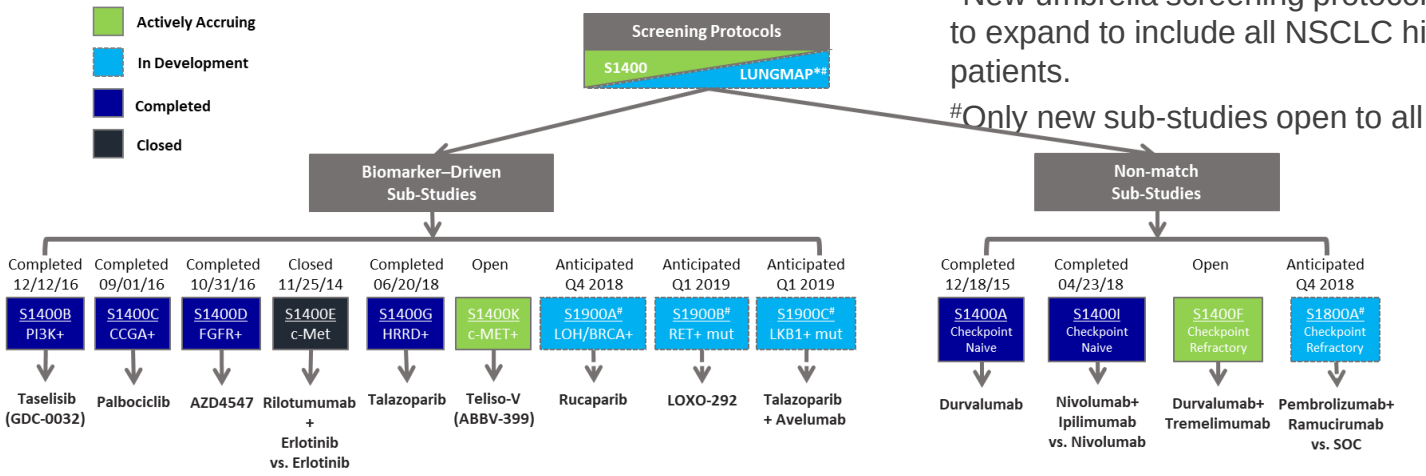



Squamous Only, SWOG, 2014

## Revision Responding to Immunotherapy Approval




## Current Schema




*New umbrella screening protocol (**LUNGMAP)** will allow the trial to expand to include all NSCLC histologies and include more patients.

#Only new sub-studies open to all NSCLC histologies.

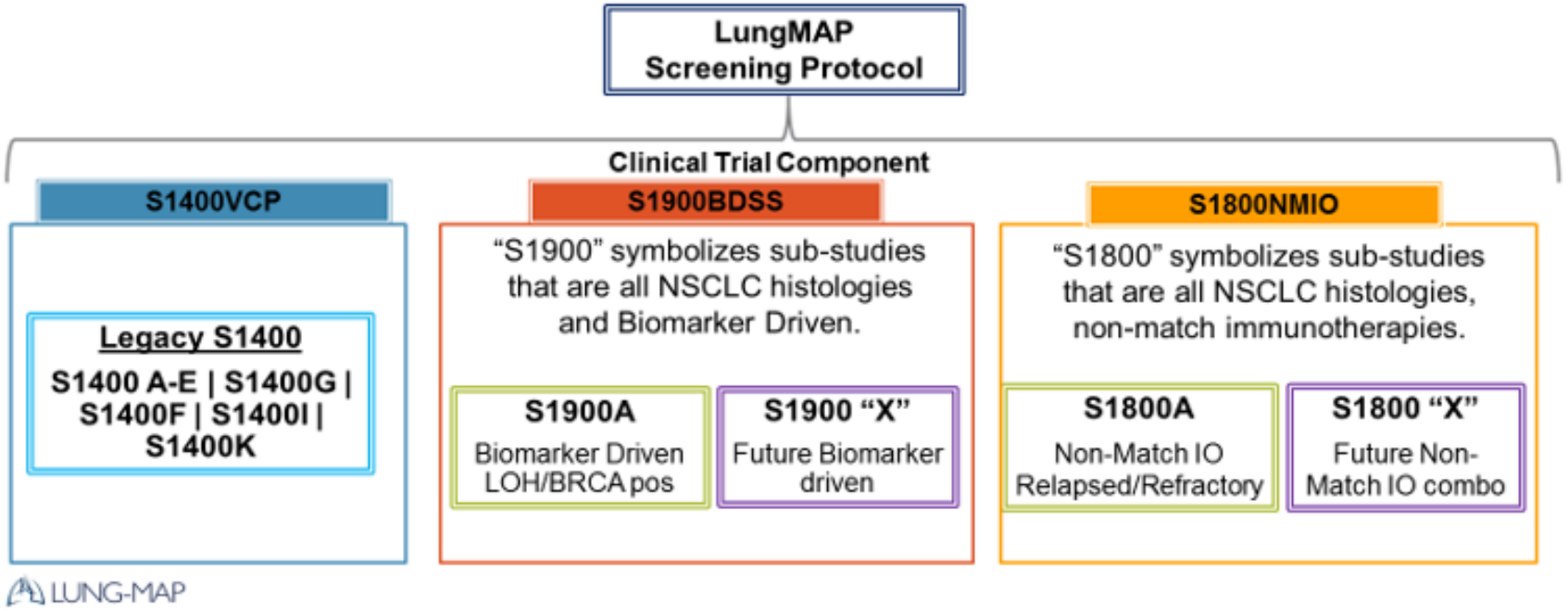
Full intergroup governance

# Protocol Infrastructure

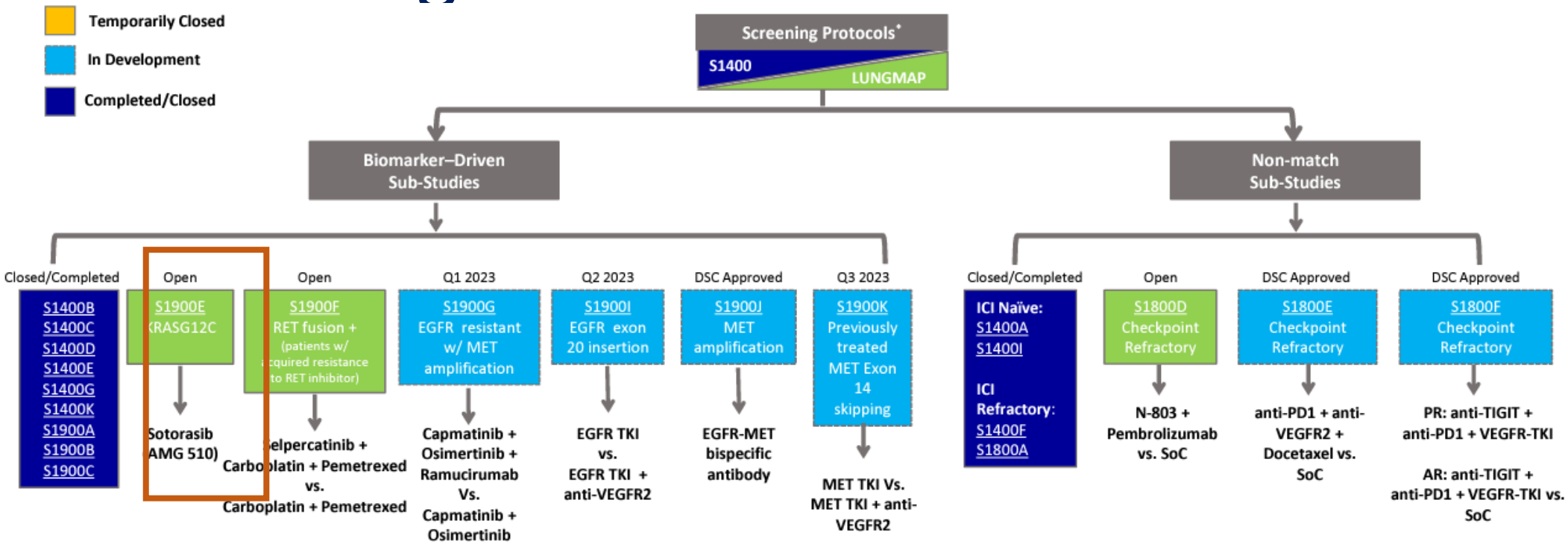
The structure of Lung-MAP has been improved with the expansion

- Standalone Protocols
- Set within a defined module (i.e. – Legacy, Biomarker-Driven, Non-Match)
- Equal governance between SWOG, Ecog/Acrin, Alliance, NRG

Flexibility of Design



# Current Lung-MAP Schema 2022

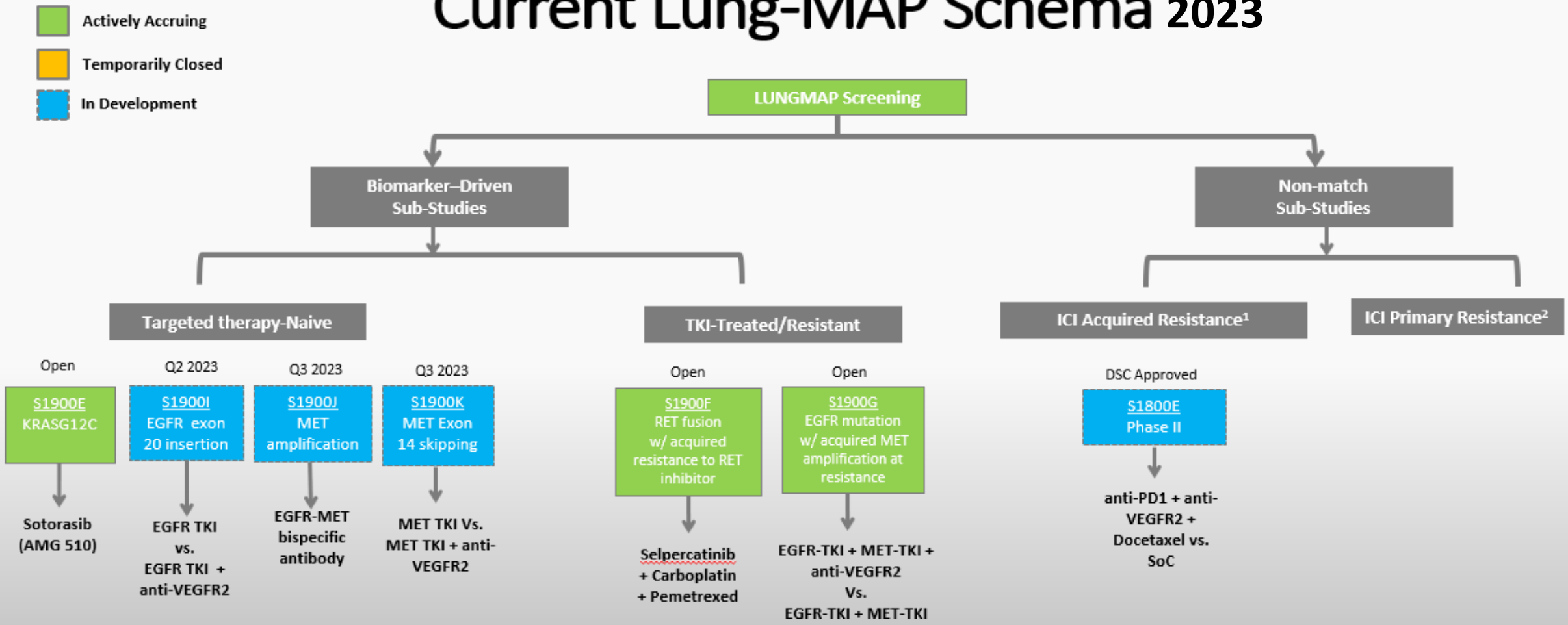



*LUNGMAP screening protocol (activated 1/28/19) allows all histologic types of NSCLC. S1400, the original screening/umbrella protocol included only squamous lung cancer. S1400 accrued patients between 6/16/2014 and 1/28/2019. While S1400 is closed to accrual, patients enrolled to S1400 may participate in sub-studies they are eligible for.

**TRIAL POINTS OF INTEREST:**

- Each of sub-study operates independently of the others
- Prescreening can be performed while the patient is on any line of therapy for stage IV disease
- Repeat or fresh biopsy necessary for tissue screening is paid by the trial
- **#Biomarker-driven sub-studies may progress to Phase III if study meets endpoint and Phase III is feasible, at which point the standard of care arm will be determined.**

# Current Lung-MAP Schema 2023




[1] Acquired Resistance is defined as progression at least (≥) 84 days from initiation of the most recent line of anti-PD-1/PD-L1 and best response of stable disease, partial response, or complete response.

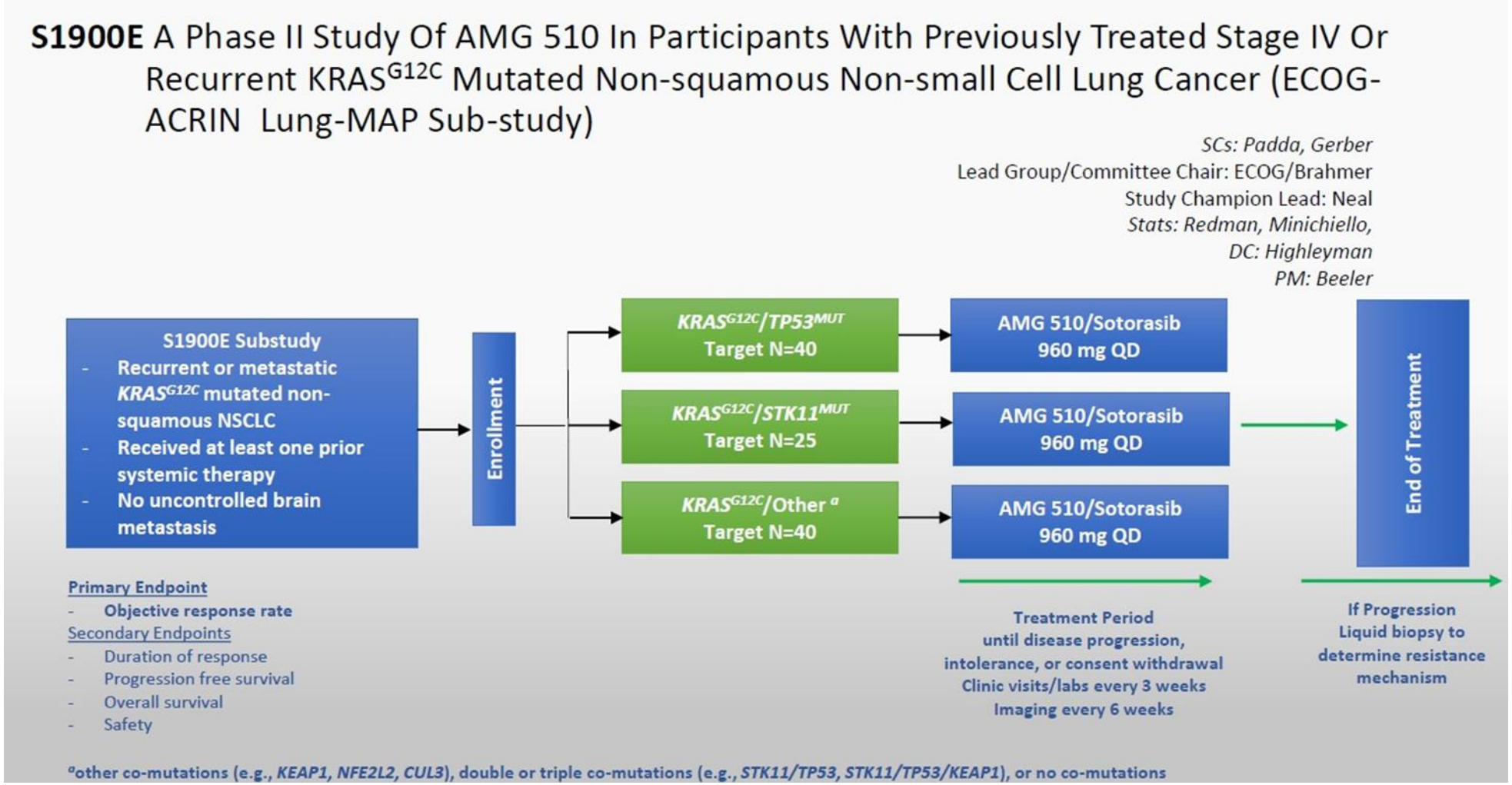
[2] Primary Resistance is defined as progression less than (<) 84 days from initiation of the most recent line of anti-PD-1/PD-L1 or best response of progressive disease.

**TRIAL POINTS OF INTEREST:**

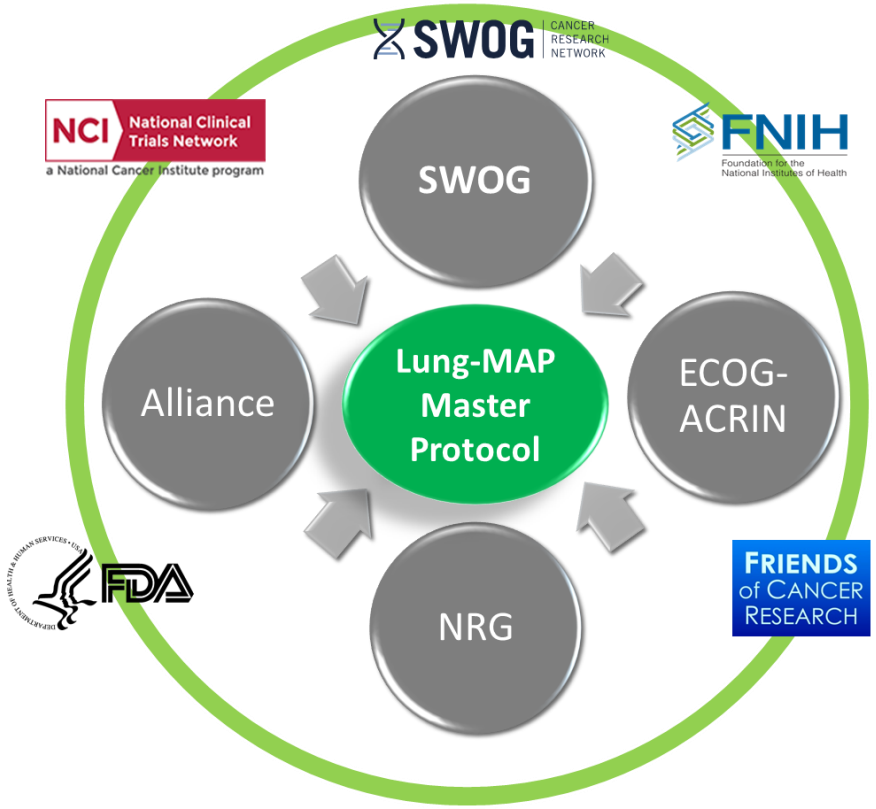
- Each of sub-study operates independently of the others
- Prescreening can be performed while the patient is on any line of therapy for stage IV disease
- Repeat or fresh biopsy necessary for tissue screening is paid by the trial
- #Biomarker-driven sub-studies may progress to Phase III if study meets endpoint and Phase III is feasible, at which point the standard of care arm will be determined.

LUNG-MAP

# Sub-study: S1900E



# #3 Cohesive project management is crucial




- Neutral third-party purse-holder, project manager, and contractor is beneficial
- Migration to a centralized IRB and introducing other protocol efficiencies is crucial for long-term survival and enrollment in the trial

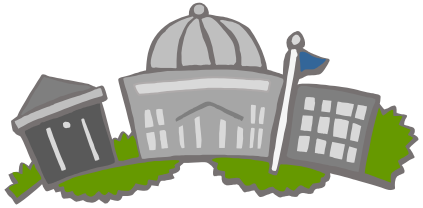
# Foundation for the National Institutes of Health

Stacey Adam, PhD

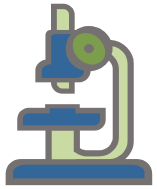
Jennifer Newsome

Taqwa El-Hussein

Established by Congress in 1990; began work in 1996



Key roles: establish and manage research collaborations, serve as neutral convener, fundraiser, program entrepreneur



Focus: advancing science, leveraging resources, fostering collaboration, defining ROI for stakeholders, pre-competitive efforts, public good

FNIH
Foundation for the National Institutes of Health

## 501(c)(3)

Non-governmental not-for-profit & independent Board of Directors

## More than 600

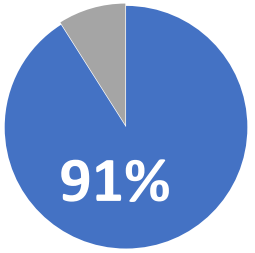
projects supported

## ~120

***active*** research partnerships, scientific education/training, conferences/events and capital programs

## $1 Billion+

raised by the FNIH since 1996




of funds directly support programs

Lung Map Trial
Approximately $100 Million to date

## 14 years

of outstanding Charity Navigator ratings

## 54

employees

# #4 Drug selection is critical with a choice of trial designs

- More than 30 formal drug selection committee meetings since 2013
  - >40 drugs
  - >20 companies engaged in discussions
- Additional ad hoc meetings to discuss pathways and targets
- Monthly internal drug selection committee meetings started in 2017 managed by Beverly Smolich from CCS Associates

Hossein Borghaei, DO, MS
Martin Edelman, MD

Shakun Malik, MD

Saiama Waqar, MD, MBBS, MSCI

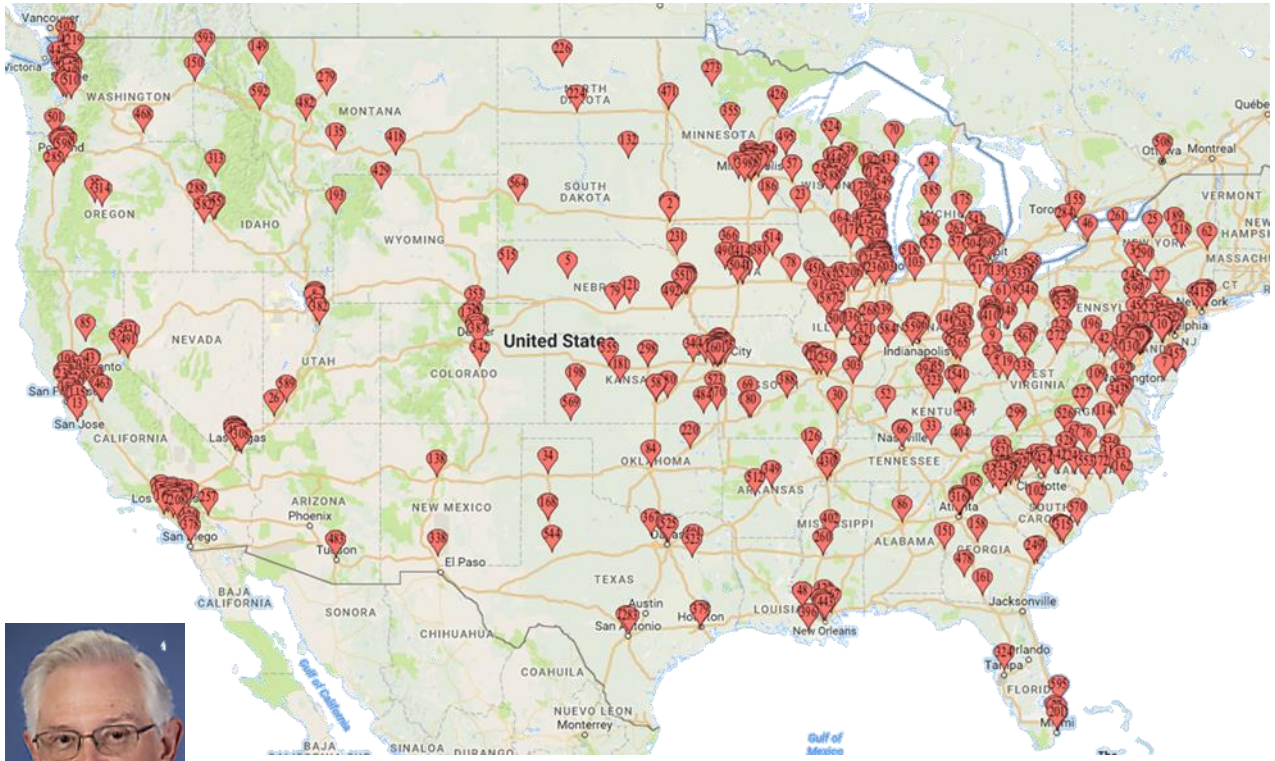
Targets and combinations evaluated since 2013:

| | | |
|---|---|---|
| c-MET | KRAS (G12) | PD-L1/TIM-3 ± PARP |
| EGFR | HDAC | HDAC/PD-1 |
| FGFR | PD-1/CTLA-4 | IL-15/PD-1 |
| PI3K | PD-L1/CTLA-4 | c-MET/EGFR/VEGFR |
| CDK4/6 | EGFR/PD-1 | TIGIT/PD-1/TKI |
| PD-L1 | c-MET, AXL | c-MET/VEGFR |
| PARP | IL-2 (Prodrug)/PD-1 | EGFR/VEGFR |
| ERBB3 | TORC1/2/CTx | PD-1/CTx/VEGFR |
| TKI | RET | |
| Glutaminase | PARP/PDL-1 | |

# #5 Pre-screening provides access to a large number of patients

| As of 07/18/23 | Total | S1400 | LUNGMAP |
|---|---|---|---|
| **Screening Registrations** | **4972** | **1864** | **3108** |
| Screened at PD | 2269 | 1127 | 1142 |
| Pre-screened | 2703 | 737 | 1966 |
| | | | |
| **Sub-study Assignments** | **3153** | **1484** | **1669** |
| Among Screened at PD | 1941 | 996 | 945 |
| Among Pre-screened | 1086 | 414 | 672 |
| Additional Assignments after PD on a Sub-study | 126 | 74 | 52 |
| | | | |
| **Sub-study Registrations** | **1143** | **690** | **453** |

~4,600 patients screened since 2014






David Gandara, MD

# #6 Improved clinical trial diversity

Riha Vaidya, PhD

Mary Redman, PhD

| | Lung-MAP (N=3,556) | SWOG NSCLC (N=2,215) | US NSCLC Population |
|---|---|---|---|
| Age ≥ 65 years | 57.2% | 46.3% * | 69.8% * |
| Female | 38.6% | 47.2% * | 46.0% * |
| Race: Black | 9.2% | 8.2% | 14.1% * |
| Race: Asian/Pacific Islander | 2.8% | 5.1% * | 4.8% * |
| Race: Native American | 0.5% | 0.4% | 0.5% |
| Ethnicity: Hispanic | 2.4% | 3.8% * | 5.1% * |
| Rural residence | 17.3% | 14.4% * | -- § |
| Areas with highest social needs | 42.2% | 36.7% * | -- § |
| Medicaid/No Insurance (if age < 65 years) | 27.6% | 17.8% * | -- § |

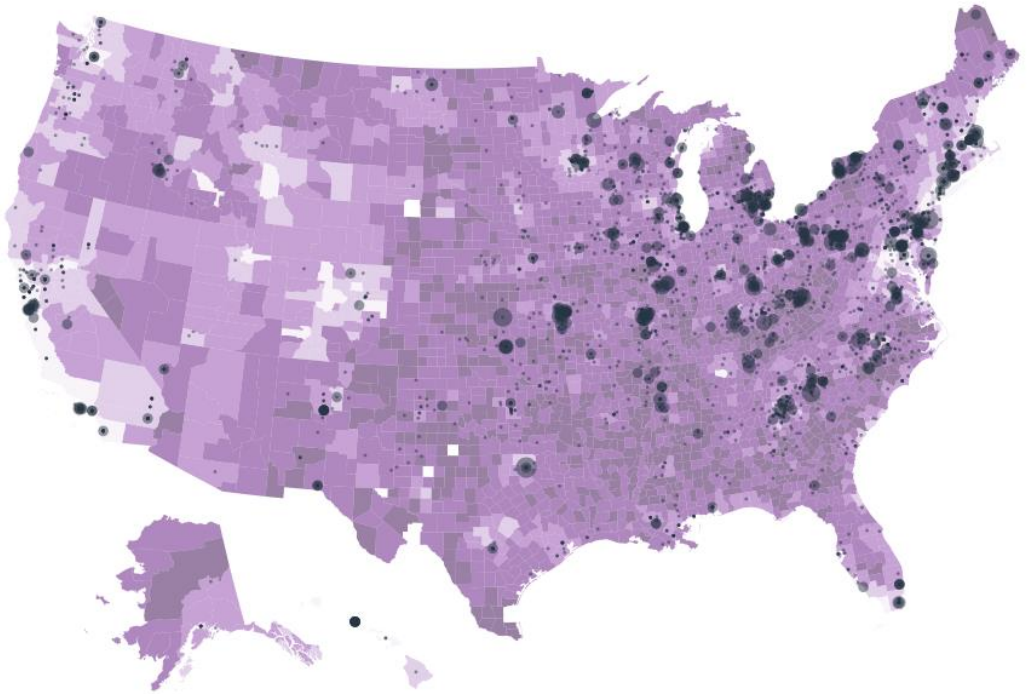
* Difference versus Lung-MAP statistically significant (p<0.01)

§ No population-level data available for geographic/SES comparisons

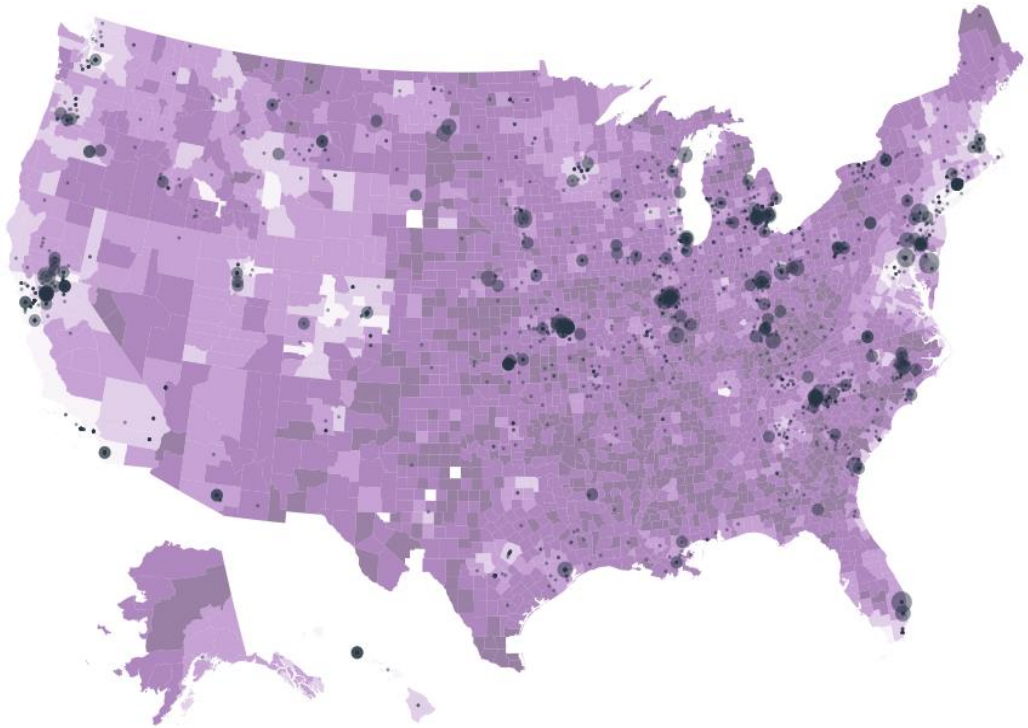
Vaidya R, Unger JM, Qian L, et al. Representativeness of Patients Enrolled in the Lung Cancer Master Protocol (Lung-MAP). JCO Precis Oncol. 2023;7:e2300218. doi:10.1200/PO.23.00218

# Enrollment by Area Deprivation (Rural)

LUNGMAP Accruals 1/1/2014 - 12/31/2020

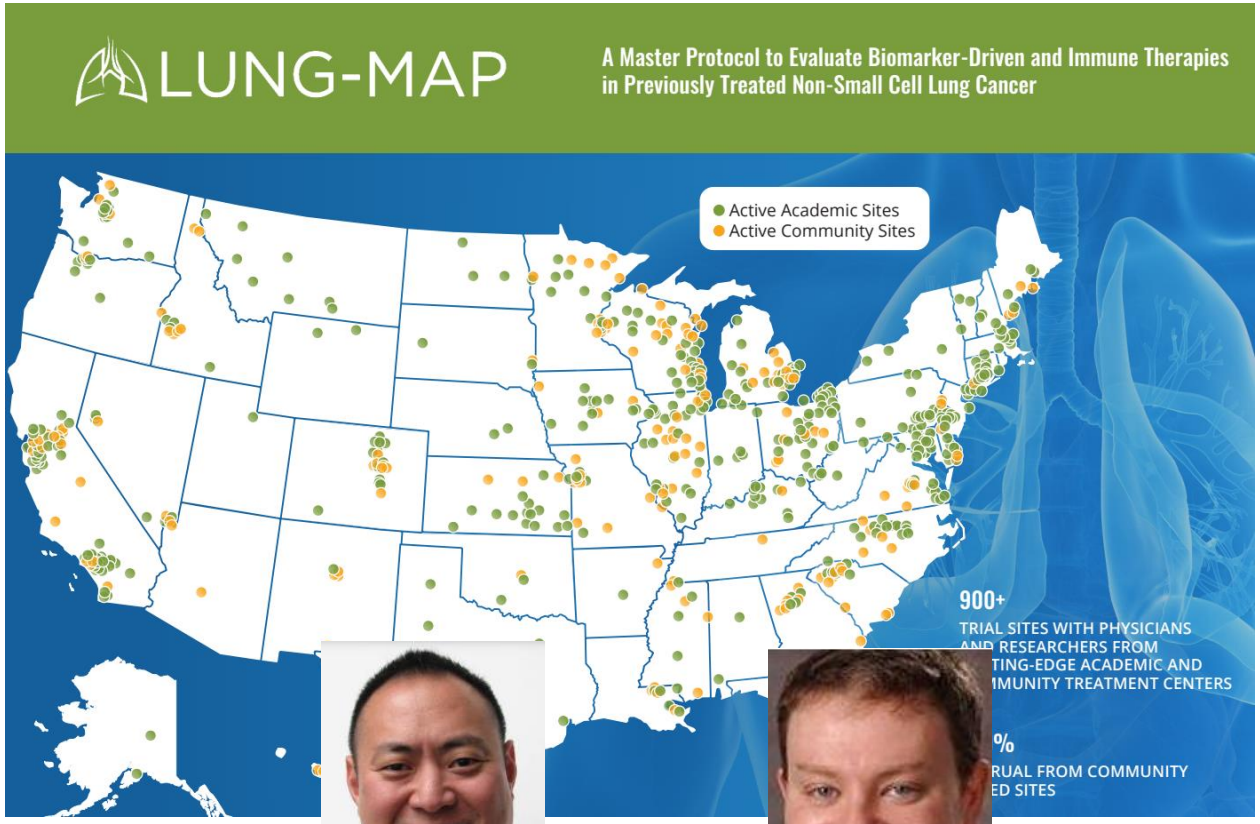


NSCLC Studies Accruals 1/1/2001 - 12/31/2020



# #7 Translational medicine is our future

- Scientifically driven clinical trials
- Comprehensive NGS tissue screening leads to assignment to biomarker-driven sub-study or enrollment on a “non-match” sub-study
- Represents a significant patient molecular resource (>2,700 screened patients; >25,000 specimens) from a real-world population (50% accrual from community sites).
- Ongoing, multi-level data analyses leading to translational medicine publications in preparation






David Kozono MD, PhD

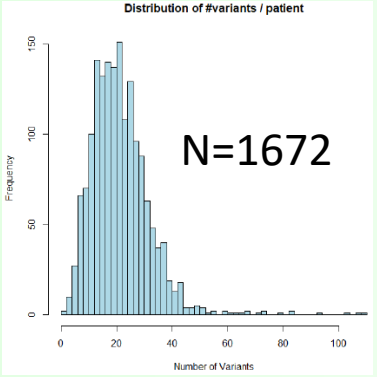


Philip Mack, PhD

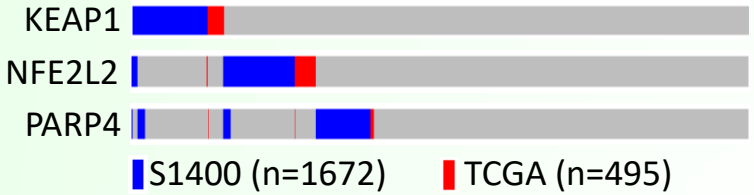
Karen Reckamp, MD, MS

# Lung-MAP Translational Medicine

## S1400: Largest NGS dataset of advanced squa. cell lung cancers of previously treated patients

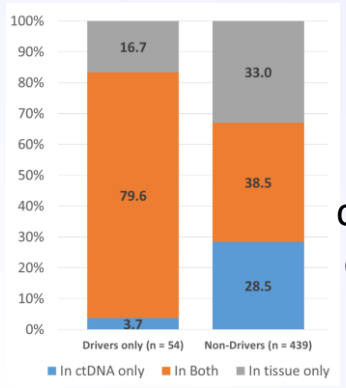



Novel finding: mutual exclusivity of PARP4, KEAP1 & NFE2L2 alterations

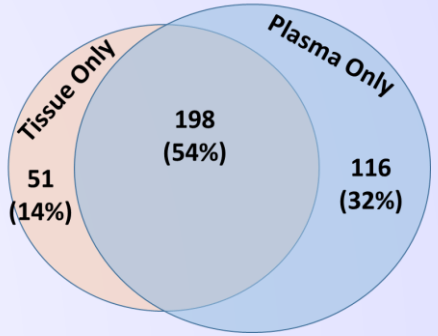



Kozono et al. WCLC 2020

## Use of liquid biopsy data in LUNGMAP



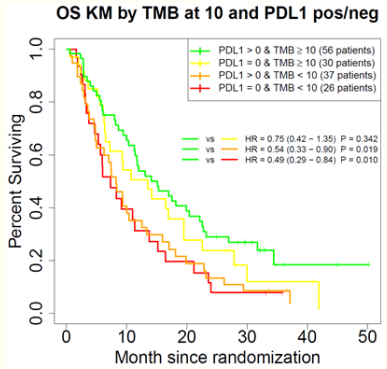

High tumor tissue-ctDNA concordance supports use of mutations found in ctDNA for enrollment onto LUNGMAP sub-studies




Mack et al. WCLC 2020

## Immuno-oncology biomarkers in S1400 sub-studies

Combination of higher tumor mutational burden (TMB) and PD-L1 expression impacted survival outcomes in the S1400I randomized study of nivolumab ± ipilimumab




Hirsch et al. WCLC 2020

## Upcoming Highlights

- Composite Immune Checkpoint Inhibitor signature for efficacy of ICI therapy in advanced squamous cell lung cancer (Gandara et al.)
- ctDNA analyses in Lung-MAP sub-studies
- Addition of protein biomarkers to Lung-MAP to facilitate novel immuno-oncology and antibody-drug conjugate sub-studies

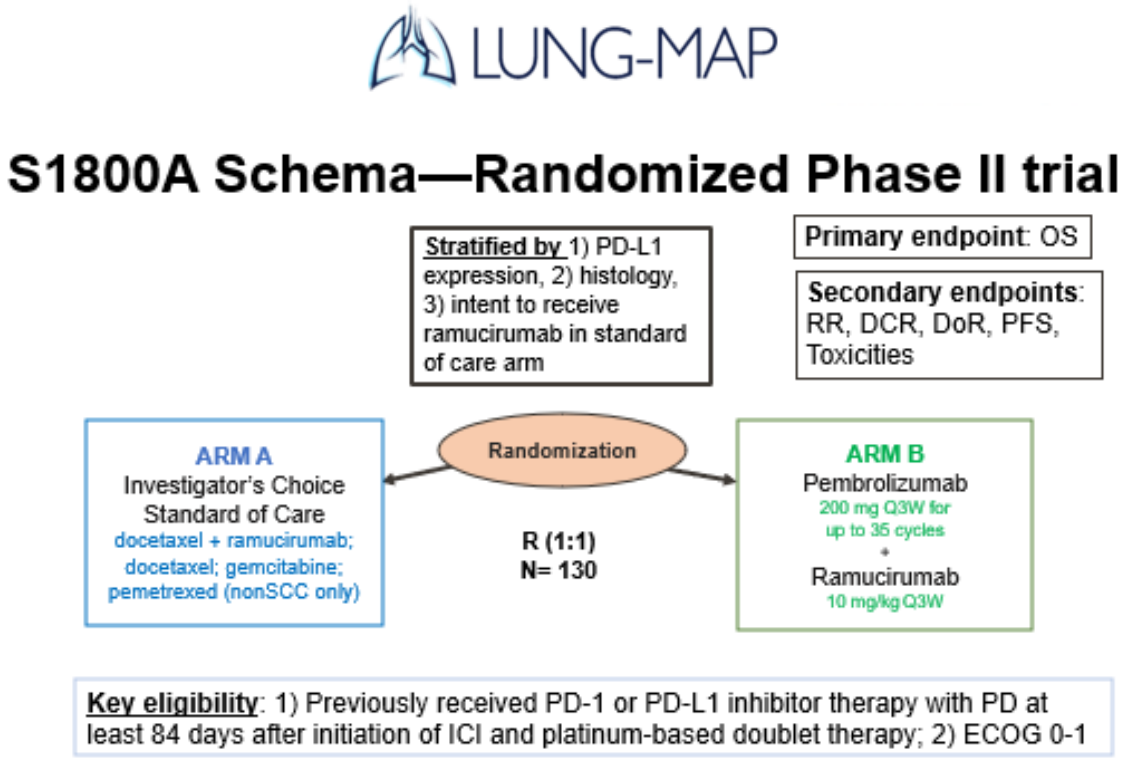
# #8 1800A: Trial Met its Primary Endpoint: ASCO 2022


Karen Reckamp, MD, MS

Konstantin H. Dragnev, MD

# S1800A: A Non-Match Sub-Study of Lung-MAP

- Patients not eligible for a biomarker-matched sub-study
- Design: Randomized Phase II
- Sample size: 130 eligible
- Primary Endpoint: Overall survival
- Primary Analysis:
  - At 1-sided 10% level
  - Testing based on better of standard log-rank and weighted log-rank test
  - Used to better detect delayed effects




NCT03971474

# #9 Pragmatica

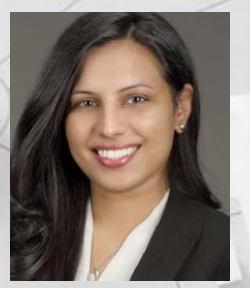
Pragmatica

A real-world clinical trial for patients whose non-small cell lung cancer has returned after immunotherapy

Breakthrough Designation Under Review

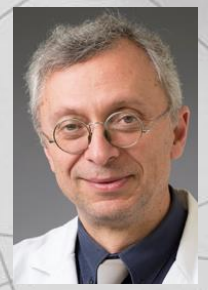
Working closely with FDA, NCI and NCTN partners on a Pragmatic trial

Richard Pazdur, MD



Harpreet Singh, MD

Karen Reckamp, MD, MS



Konstantin Dragnev, MD

Mary Redman, PhD

Ellen Sigal, PhD

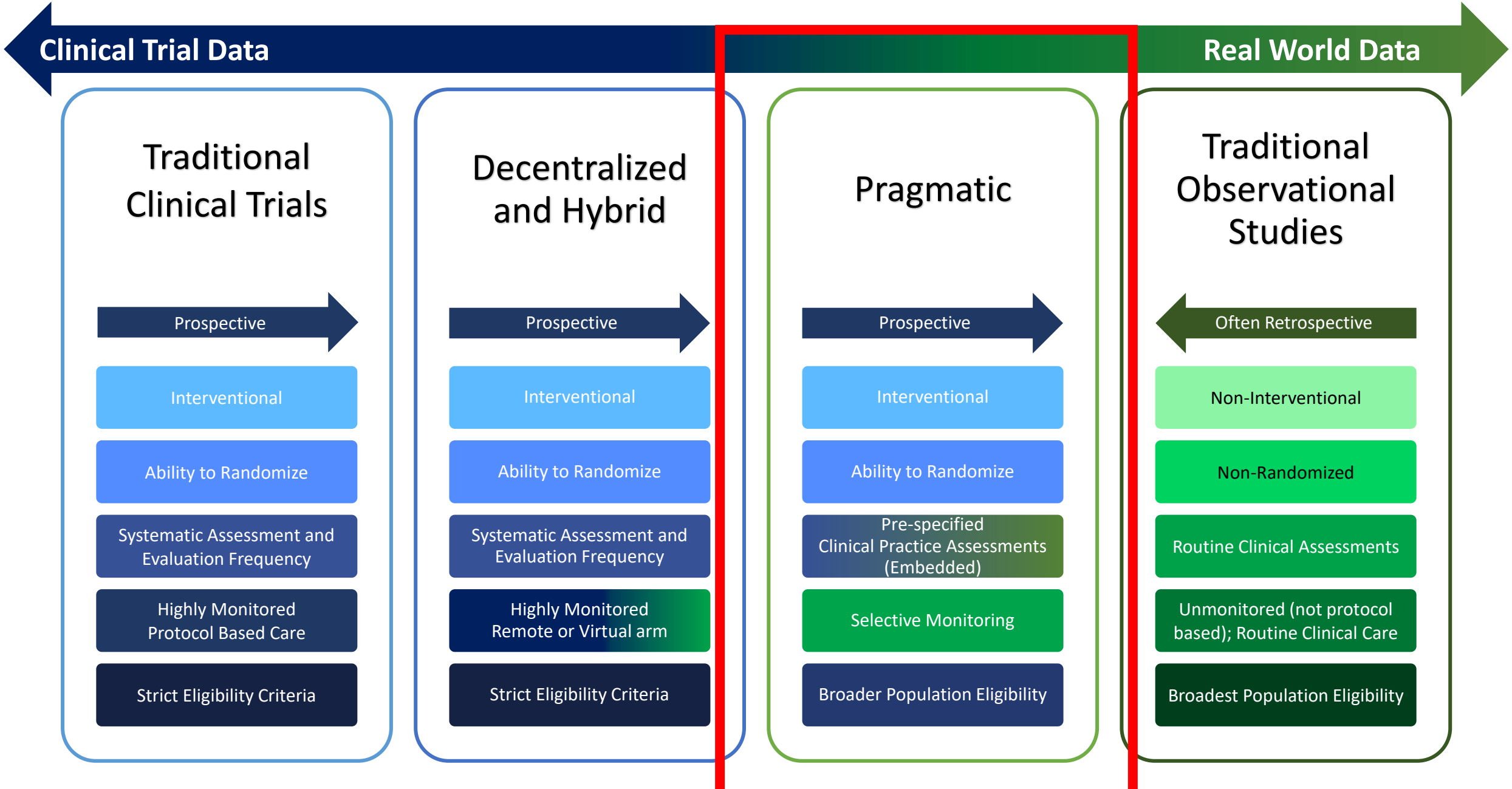
Shakun Malik, MD

Jhanelle Gray, MD

Roy Herbst, MD PhD

Lilly MERCK

# Clinical Evidence Generation Continuum



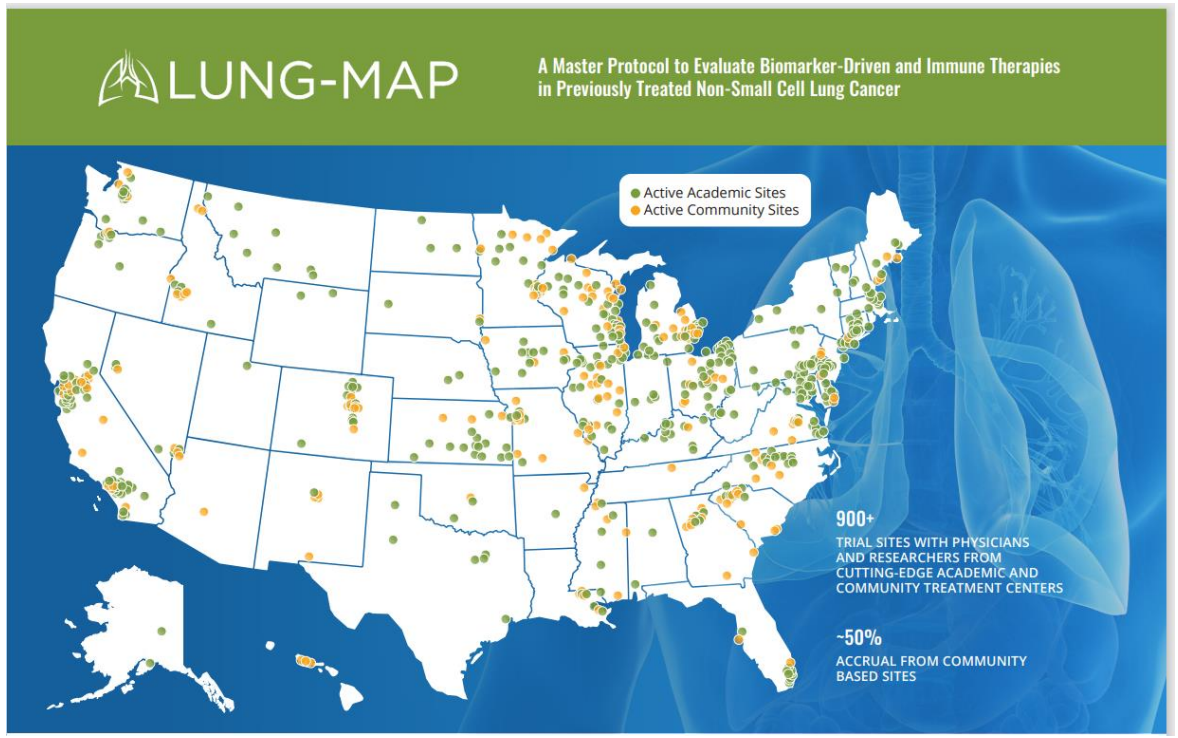
# #10 It's about the patient


***I am more confident than I have been in a long time. Lung-MAP gave me my life back.*** *~ Clifford C.*

**Most importantly, we are grateful Lung-MAP has helped many patients and we want to amplify our success so far by opening the trial to more patients!**

***I continue to be so grateful for everyone involved. Even after 48 visits for my opdivo infusion!***
*~ Annie B.*

# And We Have Helped Many Patients
# Lung Map By the Numbers




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

**13**
PARTNERING PRECISION MEDICINE DIAGNOSTIC COMPANIES AND LEADING PHARMACEUTICAL COMPANIES

**15**
INVESTIGATIONAL DRUGS OR DRUG COMBINATIONS TESTED

**16 Initiated | 14 Completed**
SUB-STUDIES CONDUCTED

**10**
AGENTS AGAINST SPECIFIC TUMOR MUTATIONS/GENETIC SIGNATURES TESTED IN NSCLC

**12**
MONTH AVERAGE SUB-STUDY STAND UP TIME FROM APPROVAL BY THE LUNG-MAP DRUG SELECTION COMMITTEE TO ACTIVATION

**22**
MONTH AVERAGE TIME TO TARGET ACCRUAL COMPLETION FOR ~80 PERSON STUDY, DRIVEN BY BIOMARKER PREVALENCE

**7**
SUPPORTING PATIENT ADVOCACY GROUPS

**~4,250 | ~650 Per Year**
PATIENTS SCREENED

**~2,750**
PATIENTS ELIGIBLE FOR A TREATMENT IN A WELL-DESIGNED TRIAL

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

**300+**
ALTERED GENES INTERROGATED IN EACH PATIENT'S TUMOR

**24%**
UNDERSERVED MINORITY PARTICIPANTS ENROLLED

**8**
ORGANIZATIONS, INCLUDING **NCI** AND **FDA**, WORKING TOGETHER TO CONDUCT AND OVERSEE THE STUDY

**10,000+**
ANNOTATED SPECIMENS IN A TISSUE BANK TO ALLOW DEEPER SCIENTIFIC STUDIES TO INFLUENCE FUTURE TRIALS

**35+**
PUBLICATIONS AND ABSTRACTS

### Additional Benefits of Lung-MAP

SHARED COSTS AND RISKS OF TESTING THERAPEUTICS FOR COMPANIES

FOSTERING DRUG COMBINATION COLLABORATIONS BETWEEN COMPANIES

ACCELERATED TIMEFRAMES FOR EVALUATION OF TREATMENT EFFICACY DUE TO THE LARGE NETWORK

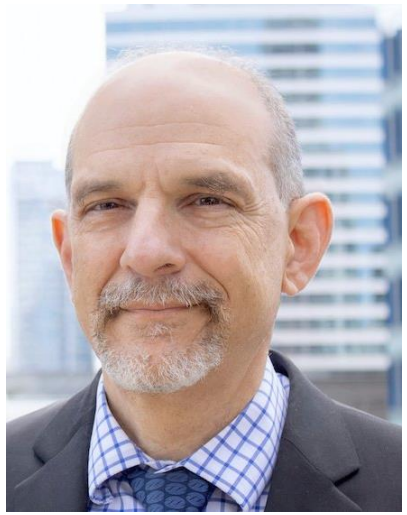
STRONG SUPPORT FROM THE FDA WITH ABILITY FOR STUDIES TO HAVE REGULATORY INTENT

### Highly Motivated Expert Partners for Trial Conduct

FNIH · FRIENDS of CANCER RESEARCH · NCI National Clinical Trials Network · SWOG · ECOG-ACRIN cancer research group · NRG ONCOLOGY · ALLIANCE

# Thoughts for the Future

- Master protocols provide efficiencies and can be very successful
- Implementation can be complicated: Oversight, conduct, and monitoring are more involved than a single study, or even the same number of independent studies
- A major lesson learned is the need for up-front planning, communication, and specification or roles.  Need for constant innovation, aggressive timelines and teamwork
- A major key to success is flexibility within a principled set of constraints
- Let the science drive the trials- learn from translational research
- Promote access and diversity- to help the most patients with NSCLC!!









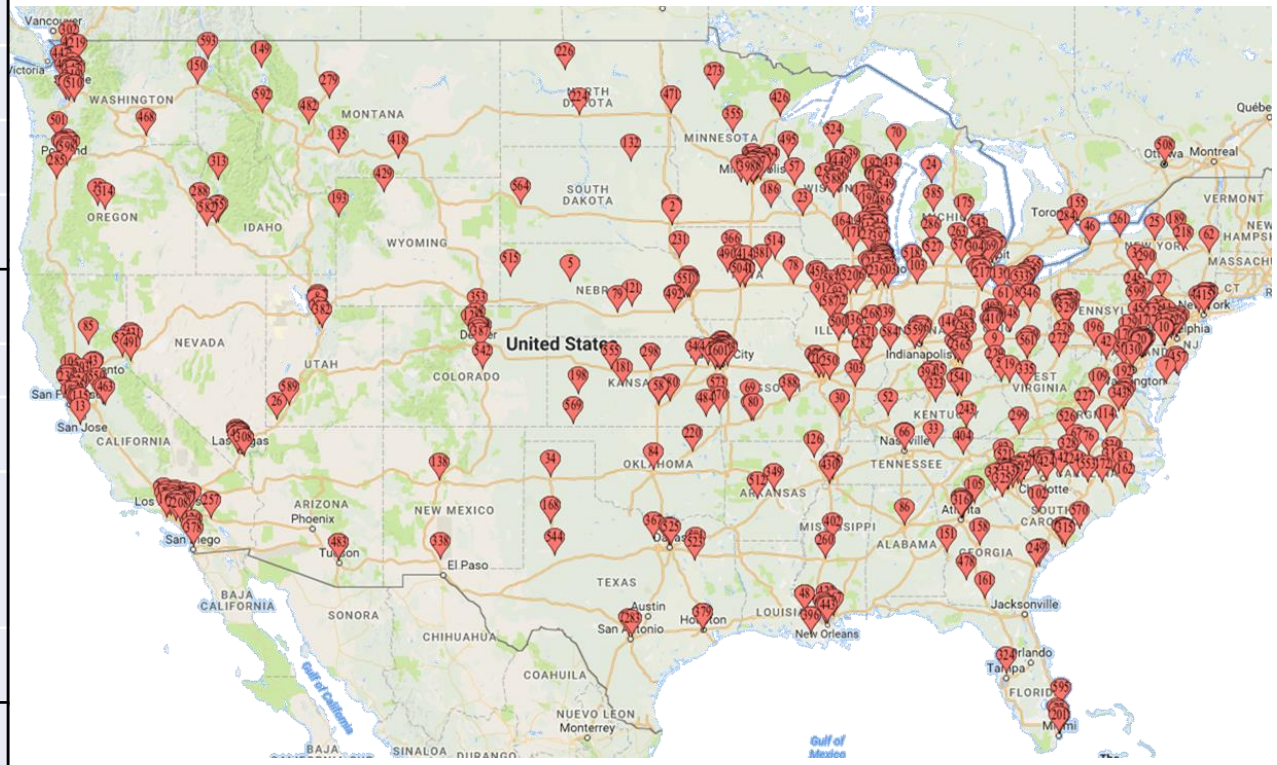




Humped
Zebra
Crossing


# Where are we now?

| As of 07/18/23 | Total | S1400 | LUNGMAP |
|---|---|---|---|
| **Screening Registrations** | **4972** | **1864** | **3108** |
| Screened at PD | 2269 | 1127 | 1142 |
| Pre-screened | 2703 | 737 | 1966 |
| | | | |
| **Sub-study Assignments** | **3153** | **1484** | **1669** |
| Among Screened at PD | 1941 | 996 | 945 |
| Among Pre-screened | 1086 | 414 | 672 |
| Additional Assignments after PD on a Sub-study | 126 | 74 | 52 |
| | | | |
| **Sub-study Registrations** | **1143** | **690** | **453** |



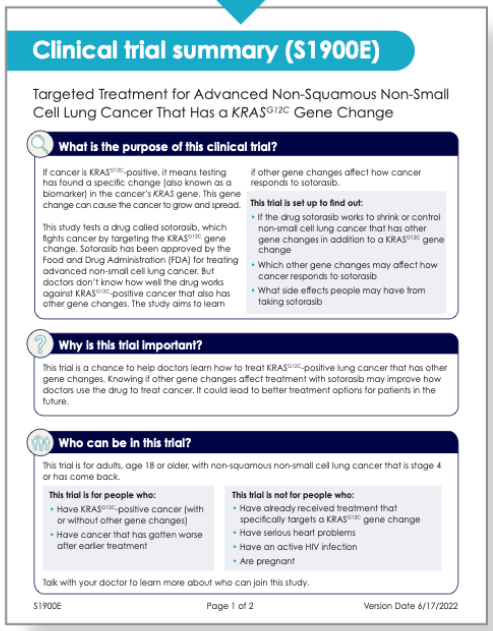
LUNG-MAP

A lung cancer precision medicine trial

# Lung-MAP Resources for You and Your Patients

**All Lung-MAP sub-studies have (or will soon have) resources for help with education and patient enrollment:**

## PATIENT-FRIENDLY PLAIN LANGUAGE TRIAL SUMMARY



Clinical trial summary (S1900E)

Targeted Treatment for Advanced Non-Squamous Non-Small Cell Lung Cancer That Has a *KRAS*$^{G12C}$ Gene Change

**What is the purpose of this clinical trial?**

If cancer is KRAS$^{G12C}$-positive, it means testing has found a specific change (also known as a biomarker) in the cancer's *KRAS* gene. This gene change can cause the cancer to grow and spread.

This study tests a drug called sotorasib, which fights cancer by targeting the KRAS$^{G12C}$ gene change. Sotorasib has been approved by the Food and Drug Administration (FDA) for treating advanced non-small cell lung cancer. But doctors don't know how well the drug works against KRAS$^{G12C}$-positive cancer that also has other gene changes. The study aims to learn if other gene changes affect how cancer responds to sotorasib.

**This trial is set up to find out:**

- If the drug sotorasib works to shrink or control non-small cell lung cancer that has other gene changes in addition to a KRAS$^{G12C}$ gene change
- Which other gene changes may affect how cancer responds to sotorasib
- What side effects people may have from taking sotorasib

**Why is this trial important?**

This trial is a chance to help doctors learn how to treat KRAS$^{G12C}$-positive lung cancer that has other gene changes. Knowing if other gene changes affect treatment with sotorasib may improve how doctors use the drug to treat cancer. It could lead to better treatment options for patients in the future.

**Who can be in this trial?**

This trial is for adults, age 18 or older, with non-squamous non-small cell lung cancer that is stage 4 or has come back.

**This trial is for people who:**

- Have KRAS$^{G12C}$-positive cancer (with or without other gene changes)
- Have cancer that has gotten worse after earlier treatment

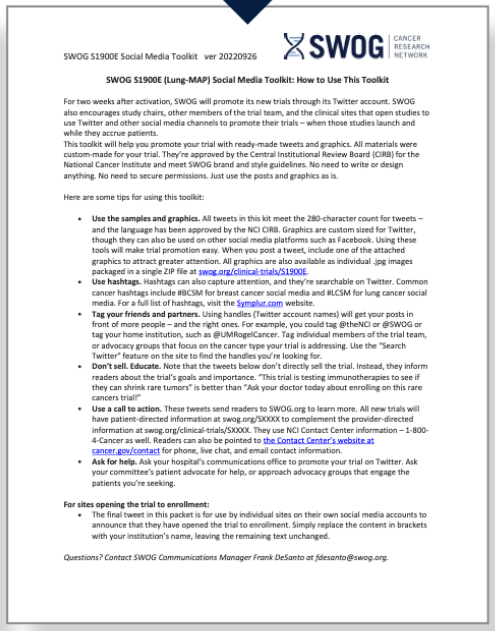
**This trial is not for people who:**

- Have already received treatment that specifically targets a KRAS$^{G12C}$ gene change
- Have serious heart problems
- Have an active HIV infection
- Are pregnant

Talk with your doctor to learn more about who can join this study.

S1900E Page 1 of 2 Version Date 6/17/2022

## SOCIAL MEDIA TOOLKIT



SWOG S1900E Social Media Toolkit ver 20220926

SWOG CANCER RESEARCH NETWORK

**SWOG S1900E (Lung-MAP) Social Media Toolkit: How to Use This Toolkit**

For two weeks after activation, SWOG will promote its new trials through its Twitter account. SWOG also encourages study chairs, other members of the trial team, and the clinical sites that open studies to use Twitter and other social media channels to promote their trials – when those studies launch and while they accrue patients.

This toolkit will help you promote your trial with ready-made tweets and graphics. All materials were custom-made for your trial. They're approved by the Central Institutional Review Board (CIRB) for the National Cancer Institute and meet SWOG brand and style guidelines. No need to write or design anything. No need to secure permissions. Just use the posts and graphics as is.

Here are some tips for using this toolkit:

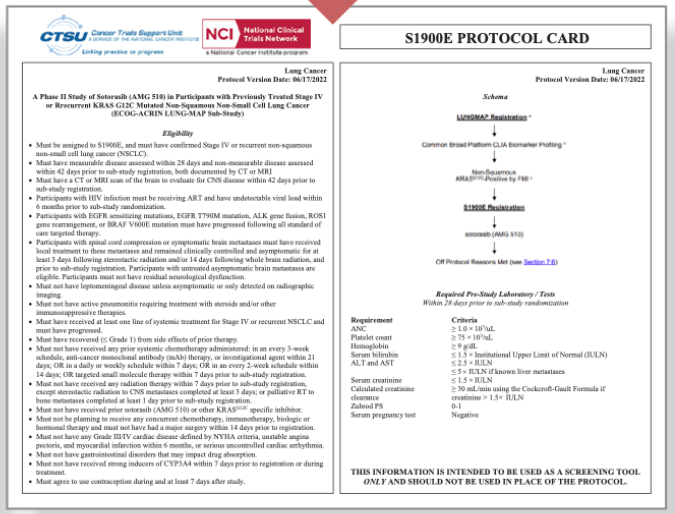
- **Use the samples and graphics.** All tweets in this kit meet the 280-character count for tweets – and the language has been approved by the NCI CIRB. Graphics are custom sized for Twitter, though they can also be used on other social media platforms such as Facebook. Using these tools will make trial promotion easy. When you post a tweet, include one of the attached graphics to attract greater attention. All graphics are also available as individual .jpg images packaged in a single ZIP file at swog.org/clinical-trials/S1900E.
- **Use hashtags.** Hashtags can also capture attention, and they're searchable on Twitter. Common cancer hashtags include #BCSM for breast cancer social media and #LCSM for lung cancer social media. For a full list of hashtags, visit the Symplur.com website.
- **Tag your friends and partners.** Using handles (Twitter account names) will get your posts in front of more people – and the right ones. For example, you could tag @theNCI or @SWOG or tag your home institution, such as @UMRogelCancer. Tag individual members of the trial team, or advocacy groups that focus on the cancer type your trial is addressing. Use the "Search Twitter" feature on the site to find the handles you're looking for.
- **Don't sell. Educate.** Note that the tweets below don't directly sell the trial. Instead, they inform readers about the trial's goals and importance. "This trial is testing immunotherapies to see if they can shrink rare tumors" is better than "Ask your doctor today about enrolling on this rare cancers trial!"
- **Use a call to action.** These tweets send readers to SWOG.org to learn more. All new trials will have patient-directed information at swog.org/SXXXX to complement the provider-directed information at swog.org/clinical-trials/SXXXX. They use NCI Contact Center information – 1-800-4-Cancer as well. Readers can also be pointed to the Contact Center's website at cancer.gov/contact for phone, live chat, and email contact information.
- **Ask for help.** Ask your hospital's communications office to promote your trial on Twitter. Ask your committee's patient advocate for help, or approach advocacy groups that engage the patients you're seeking.

**For sites opening the trial to enrollment:**

- The final tweet in this packet is for use by individual sites on their own social media accounts to announce that they have opened the trial to enrollment. Simply replace the content in brackets with your institution's name, leaving the remaining text unchanged.

*Questions? Contact SWOG Communications Manager Frank DeSanto at fdesanto@swog.org.*

## PROTOCOL CARD



CTSU Cancer Trials Support Unit — Linking practice to progress

NCI National Clinical Trials Network — a National Cancer Institute program

**S1900E PROTOCOL CARD**

Lung Cancer
Protocol Version Date: 06/17/2022

**A Phase II Study of Sotorasib (AMG 510) in Participants with Previously Treated Stage IV or Recurrent KRAS G12C Mutated Non-Squamous Non-Small Cell Lung Cancer (ECOG-ACRIN LUNG-MAP Sub-Study)**

*Eligibility*

- Must be assigned to S1900E, and must have confirmed Stage IV or recurrent non-squamous non-small cell lung cancer (NSCLC).
- Must have measurable disease assessed within 28 days and non-measurable disease assessed within 42 days prior to sub-study registration, both documented by CT or MRI.
- Must have a CT or MRI scan of the brain to evaluate for CNS disease within 42 days prior to sub-study registration.
- Participants with HIV infection must be receiving ART and have undetectable viral load within 6 months prior to sub-study randomization.
- Participants with EGFR sensitizing mutations, EGFR T790M mutation, ALK gene fusion, ROS1 gene rearrangement, or BRAF V600E mutation must have progressed following all standard of care targeted therapy.
- Participants with spinal cord compression or symptomatic brain metastases must have received local treatment to these metastases and remained clinically controlled and asymptomatic for at least 3 days following stereotactic radiation and/or 14 days following whole brain radiation, and prior to sub-study registration. Participants with untreated asymptomatic brain metastases are eligible. Participants must not have residual neurological dysfunction.
- Must not have leptomeningeal disease unless asymptomatic or only detected on radiographic imaging.
- Must not have active pneumonitis requiring treatment with steroids and/or other immunosuppressive therapies.
- Must have received at least one line of systemic treatment for Stage IV or recurrent NSCLC and must have progressed.
- Must have recovered (≤ Grade 1) from side effects of prior therapy.
- Must not have received any prior systemic chemotherapy administered: in an every 3-week schedule, anti-cancer monoclonal antibody (mAb) therapy, or investigational agent within 21 days; OR in a daily or weekly schedule within 7 days; OR in an every 2-week schedule within 14 days; OR targeted small molecule therapy within 7 days prior to sub-study registration.
- Must not have received any radiation therapy within 7 days prior to sub-study registration, except stereotactic radiation to CNS metastases completed at least 3 days; or palliative RT to bone metastases completed at least 1 day prior to sub-study registration.
- Must not have received prior sotorasib (AMG 510) or other KRAS$^{G12C}$ specific inhibitor.
- Must not be planning to receive any concurrent chemotherapy, immunotherapy, biologic or hormonal therapy and must not have had a major surgery within 14 days prior to registration.
- Must not have any Grade III/IV cardiac disease defined by NYHA criteria, unstable angina pectoris, and myocardial infarction within 6 months, or serious uncontrolled cardiac arrhythmia.
- Must not have gastrointestinal disorders that may impact drug absorption.
- Must not have received strong inducers of CYP3A4 within 7 days prior to registration or during treatment.
- Must agree to use contraception during and at least 7 days after study.

Lung Cancer
Protocol Version Date: 06/17/2022

*Schema*

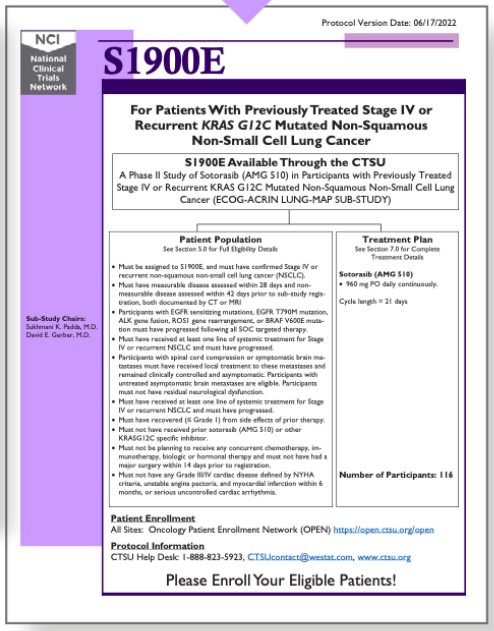
LUNGMAP Registration *
↓
Common Broad Platform CLIA Biomarker Profiling *
↓
Non-Squamous KRAS$^{G12C}$ Positive by FMI *
↓
S1900E Registration
↓
sotorasib (AMG 510)
↓
Off Protocol Reasons Met (see Section 7.6)

*Required Pre-Study Laboratory / Tests*
*Within 28 days prior to sub-study randomization*

| Requirement | Criteria |
|---|---|
| ANC | $\geq 1.0 \times 10^3$/uL |
| Platelet count | $\geq 75 \times 10^3$/uL |
| Hemoglobin | $\geq 9$ g/dL |
| Serum bilirubin | $\leq 1.5 \times$ Institutional Upper Limit of Normal (IULN) |
| ALT and AST | $\leq 2.5 \times$ IULN<br>$\leq 5 \times$ IULN if known liver metastases |
| Serum creatinine | $\leq 1.5 \times$ IULN |
| Calculated creatinine clearance | $\geq 30$ mL/min using the Cockcroft-Gault Formula if creatinine $> 1.5 \times$ IULN |
| Zubrod PS | 0-1 |
| Serum pregnancy test | Negative |

**THIS INFORMATION IS INTENDED TO BE USED AS A SCREENING TOOL *ONLY* AND SHOULD NOT BE USED IN PLACE OF THE PROTOCOL.**

## PHYSICIAN FACT SHEET



Protocol Version Date: 06/17/2022

NCI National Clinical Trials Network

**S1900E**

**For Patients With Previously Treated Stage IV or Recurrent *KRAS G12C* Mutated Non-Squamous Non-Small Cell Lung Cancer**

**S1900E Available Through the CTSU**

A Phase II Study of Sotorasib (AMG 510) in Participants with Previously Treated Stage IV or Recurrent KRAS G12C Mutated Non-Squamous Non-Small Cell Lung Cancer (ECOG-ACRIN LUNG-MAP SUB-STUDY)

**Patient Population**
See Section 5.0 for Full Eligibility Details

- Must be assigned to S1900E, and must have confirmed Stage IV or recurrent non-squamous non-small cell lung cancer (NSCLC).
- Must have measurable disease assessed within 28 days and non-measurable disease assessed within 42 days prior to sub-study registration, both documented by CT or MRI.
- Participants with EGFR sensitizing mutations, EGFR T790M mutation, ALK gene fusion, ROS1 gene rearrangement, or BRAF V600E mutation must have progressed following all SOC targeted therapy.
- Must have received at least one line of systemic treatment for Stage IV or recurrent NSCLC and must have progressed.
- Must have recovered (≤ Grade 1) from side effects of prior therapy.
- Must not have received prior sotorasib (AMG 510) or other KRASG12C specific inhibitor.
- Must not be planning to receive any concurrent chemotherapy, immunotherapy, biologic or hormonal therapy and must not have had a major surgery within 14 days prior to registration.
- Must not have any Grade III/IV cardiac disease defined by NYHA criteria, unstable angina pectoris, and myocardial infarction within 6 months, or serious uncontrolled cardiac arrhythmia.

**Treatment Plan**
See Section 7.0 for Complete Treatment Details

**Sotorasib (AMG 510)**
- 960 mg PO daily continuously.

Cycle length = 21 days

**Number of Participants: 116**

**Sub-Study Chairs:**
Sukhmani K. Padda, M.D.
David E. Gerber, M.D.

**Patient Enrollment**
All Sites: Oncology Patient Enrollment Network (OPEN) https://open.ctsu.org/open

**Protocol Information**
CTSU Help Desk: 1-888-823-5923, CTSUcontact@westat.com, www.ctsu.org

Please Enroll Your Eligible Patients!

**You can download and print these resources from CTSU.org or from SWOG.org.**

# LUNG-MAP

A lung cancer precision medicine trial

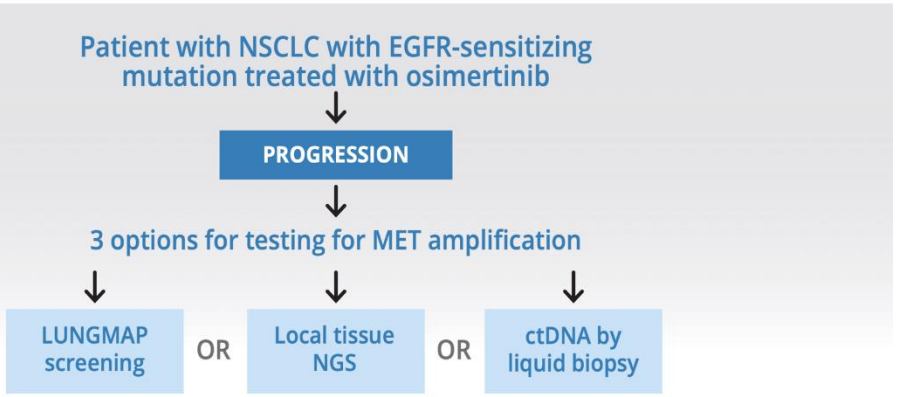
VOLUME 23 | SUMMER 2023 NEWSLETTER WWW.LUNG-MAP.ORG

## S1900G Is Open and Enrolling: MET-amplified, EGFR-mutant NSCLC

**Lung-MAP's newest sub-study** is enrolling patients with an EGFR mutation whose disease has progressed on osimertinib because of MET gene amplification.

Patients with advanced EGFR-mutant non-small cell lung cancer often do well on an EGFR inhibitor such as osimertinib, but their disease eventually becomes resistant. If this resistance is caused by MET amplification, the patient may be a candidate for S1900G. Patients are randomized to capmatinib and osimertinib with or without ramucirumab.

If your patient's NSCLC has progressed on osimertinib, consider screening them for Lung-MAP and S1900G.




### Sneak Peek: S1900K Is Just Around the Corner

Lung-MAP's newest biomarker sub-study, expected to activate later this summer, is S1900K. It is being designed for patients with MET exon 14 skipping-positive non-small cell lung cancer and will randomize them to a MET inhibitor alone or in combination with a VEGFR2 inhibitor. Watch your protocol broadcasts to learn when this sub-study will launch.

LEARN MORE AT **WWW.LUNG-MAP.ORG**

NCI National Clinical Trials Network | SWOG Cancer Research Network | FNIH Foundation for the National Institutes of Health | Friends of Cancer Research | Alliance for Clinical Trials in Oncology | ECOG-ACRIN cancer research group | NRG Oncology