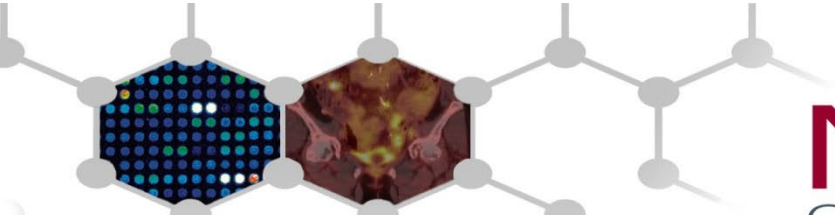

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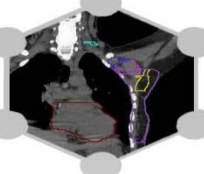
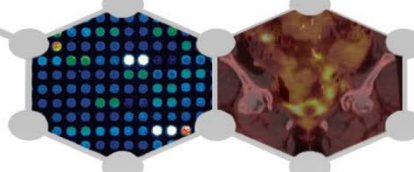


LUNG-MAP
Lung Master Protocol

Anjali Rohatgi, MD PhD

NRG Oncology Semi-Annual Meeting
July 2022



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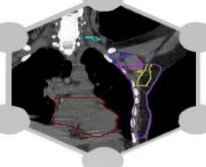


Disclosures: None

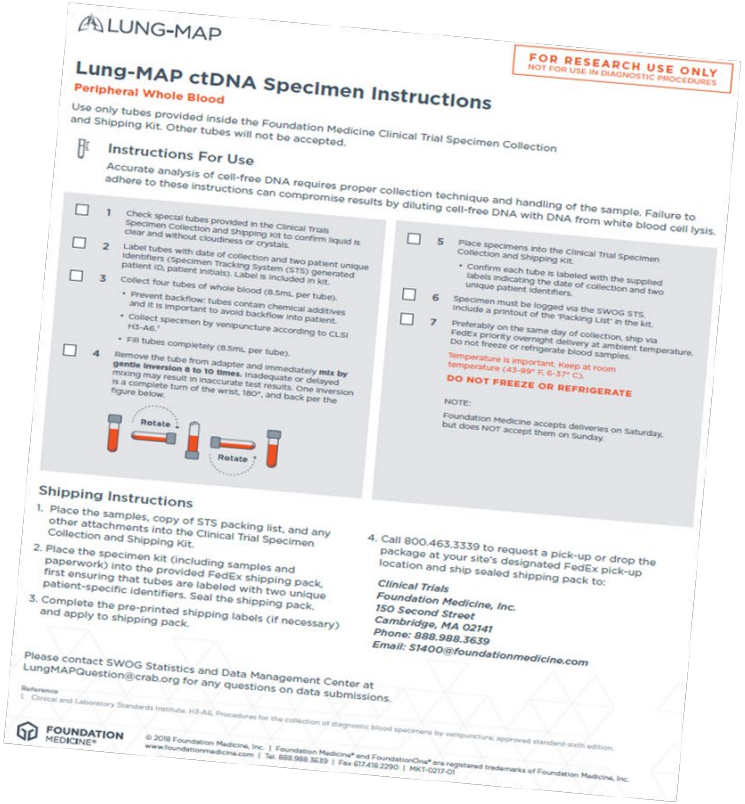
LUNGMAP Objectives

- **Title:** **A Master Protocol to Evaluate Biomarker-Driven Therapies and Immunotherapies in Previously-Treated Non-Small Cell Lung Cancer (Lung-MAP Screening Study)**
- **Primary Objectives**
  - Test patient specimens to determine eligibility for participation in the biomarker-driven and non-matched sub-studies included within the Lung-MAP umbrella protocol.
- **Secondary Objectives**
  - Screening Success Rate Objective
    - To evaluate the screen success rate defined as the percentage of screened patients that register for at therapeutic sub-study. Screen success rates will be evaluated for the total screened population and by the subset of patients screened following progression on previous therapy or pre-screened on current therapy.
  - Translational Medicine Objective
    - 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.

Summary of Screening Protocol-LUNGMAP

- Inclusion of all histologic types of NSCLC
- Expand to allow patients with known driver-mutations after progression on all standard of care targeted therapies.
- Inclusion of liquid biopsy:
  - At screening, for comparison with those undergoing fresh tissue biopsy
  - To all sub-studies
  - Assessment of TMB and allelic frequency (potential serial sampling for early prediction of outcome)
- PD-L1 testing on all patients
- All sites must use the central IRB (cIRB)

Foundation One testing



LUNG-MAP

FOR RESEARCH USE ONLY
NOT FOR USE IN DIAGNOSTIC PROCEDURES

Lung-MAP ctDNA Specimen Instructions

Peripheral Whole Blood

Use only tubes provided inside the Foundation Medicine Clinical Trial Specimen Collection and Shipping Kit. Other tubes will not be accepted.

Instructions For Use

Accurate analysis of cell-free DNA requires proper collection technique and handling of the sample. Failure to adhere to these instructions can compromise results by diluting cell-free DNA with DNA from white blood cell lysis.

1. Check special tubes provided in the Clinical Trials Specimen Collection and Shipping Kit to confirm liquid is clear and without cloudiness or crystals.
2. Label tubes with date of collection and two patient unique identifiers (Specimen Tracking System (STS) generated patient ID, patient initials). Label is included in kit.
3. Collect four tubes of whole blood (8.5mL per tube).
   - Prevent backflow: tubes contain chemical additives and it is important to avoid backflow into patient.
   - Collect specimen by venipuncture according to CLSI H3-A6.[1]
   - Fill tubes completely (8.5mL per tube).
4. Remove the tube from adapter and immediately **mix by gentle inversion 8 to 10 times.** Inadequate or delayed mixing may result in inaccurate test results. One inversion is a complete turn of the wrist, 180°, and back per the figure below.

Rotate Rotate

5. Place specimens into the Clinical Trial Specimen Collection and Shipping Kit.
   - Confirm each tube is labeled with the supplied labels indicating the date of collection and two unique patient identifiers.
6. Specimen must be logged via the SWOG STS. Include a printout of the 'Packing List' in the kit.
7. Preferably on the same day of collection, ship via FedEx priority overnight delivery at ambient temperature. Do not freeze or refrigerate blood samples.

Temperature is important. Keep at room temperature (43-99° F, 6-37° C).

DO NOT FREEZE OR REFRIGERATE

NOTE:

Foundation Medicine accepts deliveries on Saturday, but does NOT accept them on Sunday.

Shipping Instructions

1. Place the samples, copy of STS packing list, and any other attachments into the Clinical Trial Specimen Collection and Shipping Kit.
2. Place the specimen kit (including samples and paperwork) into the provided FedEx shipping pack, first ensuring that tubes are labeled with two unique patient-specific identifiers. Seal the shipping pack.
3. Complete the pre-printed shipping labels (if necessary) and apply to shipping pack.
4. Call 800.463.3339 to request a pick-up or drop the package at your site's designated FedEx pick-up location and ship sealed shipping pack to:

Clinical Trials
Foundation Medicine, Inc.
150 Second Street
Cambridge, MA 02141
Phone: 888.988.3639
Email: S1400@foundationmedicine.com

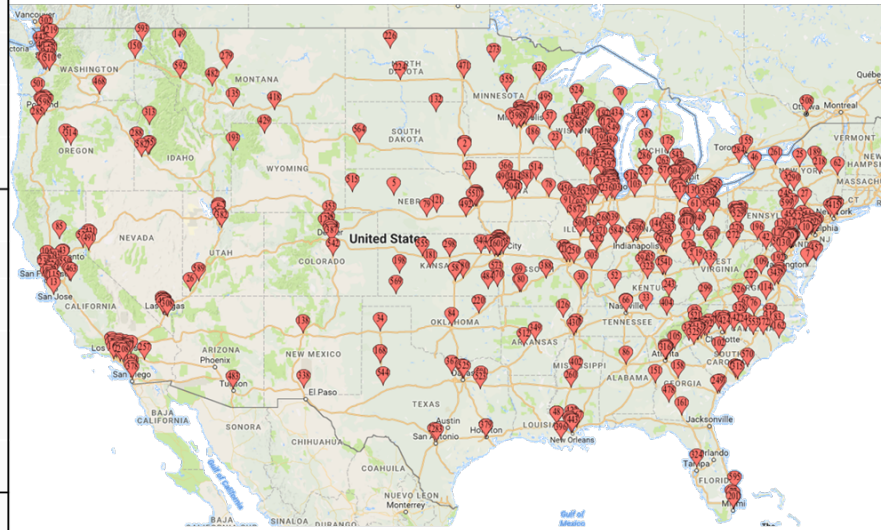
Please contact SWOG Statistics and Data Management Center at LungMAPQuestion@crab.org for any questions on data submissions.

Reference
1. Clinical and Laboratory Standards Institute. H3-A6; Procedures for the collection of diagnostic blood specimens by venipuncture; approved standard-sixth edition.

FOUNDATION MEDICINE®

Where are we now?

As of 07/06/22	Total	S1400	LUNGMAP
Screening Registrations	**4432**	**1864**	**2568**
Screened at PD	2070	1127	943
Pre-screened*	2362	737	1625
Sub-study Assignments	**2856**	**1484**	**1372**
Among Screened at PD	1781	996	785
Among Pre-screened	954	414	540
Additional Assignments after PD on a Sub-study	121	74	47
Sub-study Registrations	**1055**	**690****	**365**



* pre-screening was added in May 2015 (11 months after activation)
** includes 21 pts registered to a LUNGMAP sub-study

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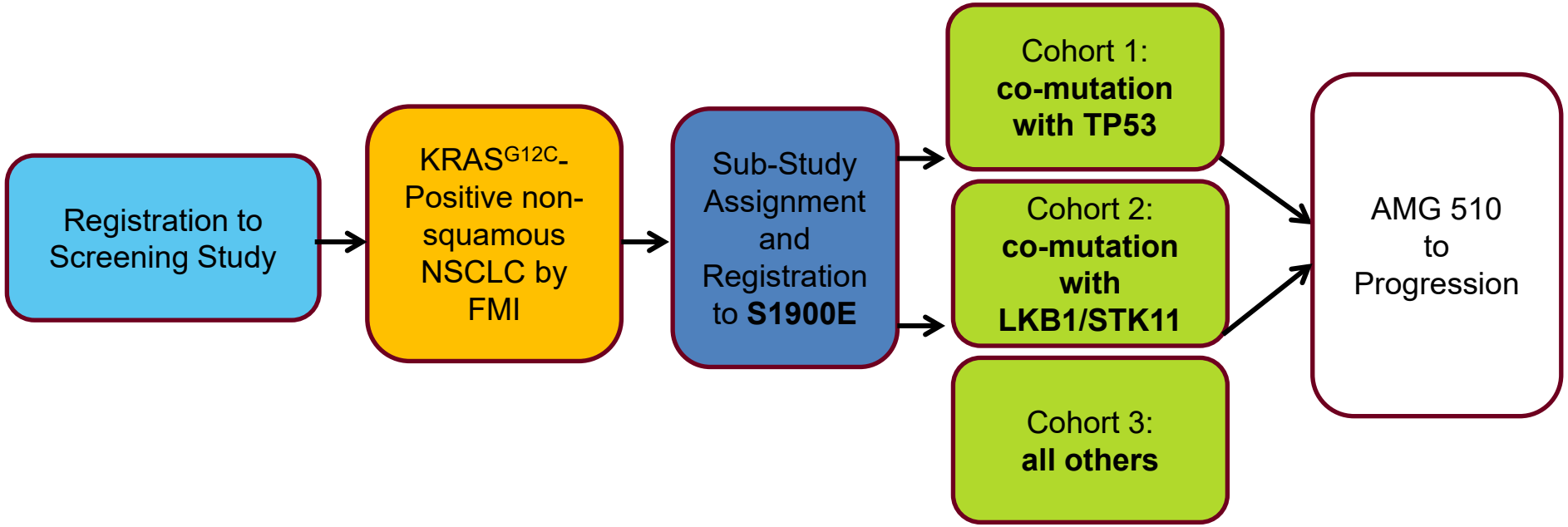
S1900E Schema



Accrual Goal: **132** patients

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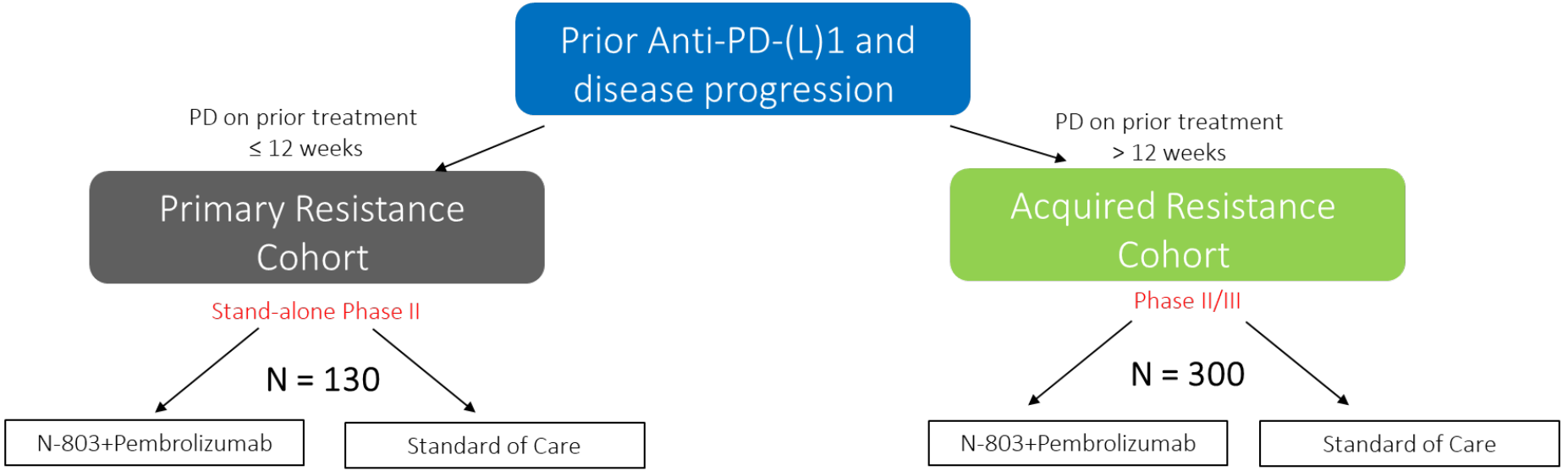
S1800D Schema



Primary Endpoint: Overall Survival
Comparison: Weighted Log-rank test
Minimum Follow-up requirements for all analyses (interim and final)

Primary Endpoint: Overall Survival
Comparison: Standard Log-rank test
Minimum Follow-up requirements for all analyses (interim and final)

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Standard of Care: Docetaxel + Ramucirumab, Docetaxel, Gemcitabine, Pemetrexed

2022 ASCO® ANNUAL MEETING

SWOG CANCER RESEARCH NETWORK | NCI National Clinical Trials Network | NCI Community Oncology Research Program

Overall survival from a phase II randomized study of ramucirumab plus pembrolizumab versus standard of care for advanced non-small cell lung cancer previously treated with immunotherapy—Lung-MAP non-matched sub-study S1800A

Karen L. Reckamp, M.D.[1], Mary W. Redman, PhD[2], Konstantin H. Dragnev, M.D.[3], Liza Villaruz, M.D.[4], Bryan Faller, MD[5]; Tareq Al Baghdadi, MD[6], Susan Hines, MD[7], Lu Qian, M.S.[2], Katherine Minichiello, M.S.[2], David R. Gandara, M.D.[8], Karen Kelly, MD[8], Roy S. Herbst, M.D., Ph.D.[9]

[1]Cedars-Sinai Medical Center, Los Angeles, CA; [2]SWOG Statistics and Data Management Center & Fred Hutchinson Cancer Research Center, Seattle, WA; [3]Dartmouth-Hitchcock Norris Cotton Cancer Center, Lebanon, NH/Alliance for Clinical Trials in Cancer; [4]University of Pittsburgh Medical Center (UPMC) Hillman Cancer Center; [5]Missouri Baptist Medical Center, St. Louis, MO/Heartland NCORP; [6]IHA Hematology Oncology Consultants-Ann Arbor/Michigan CRC NCORP; [7]Novant Health Cancer Institute - Mount Airy/Southeast Clinical Oncology Research Consortium NCORP); [8]UC Davis Comprehensive Cancer Center, Sacramento, CA; [9]Yale University, New Haven, CT

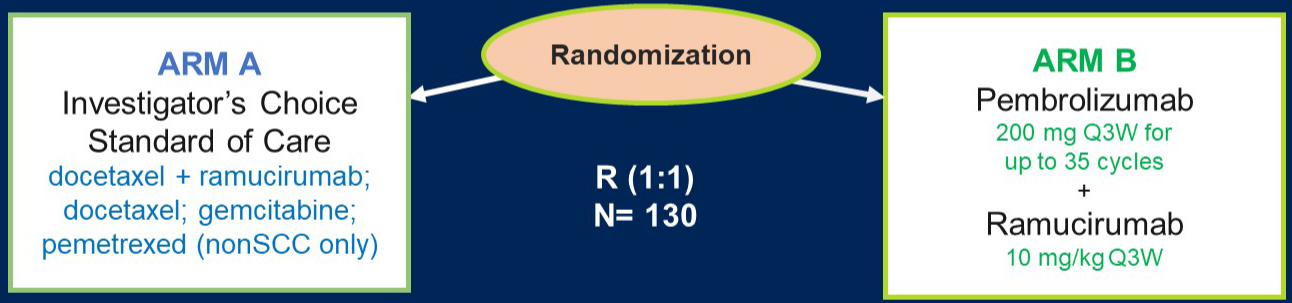
S1800A Schema—Randomized Phase II trial

NCT03971474

Stratified by 1) PD-L1 expression, 2) histology, 3) intent to receive ramucirumab in standard of care arm

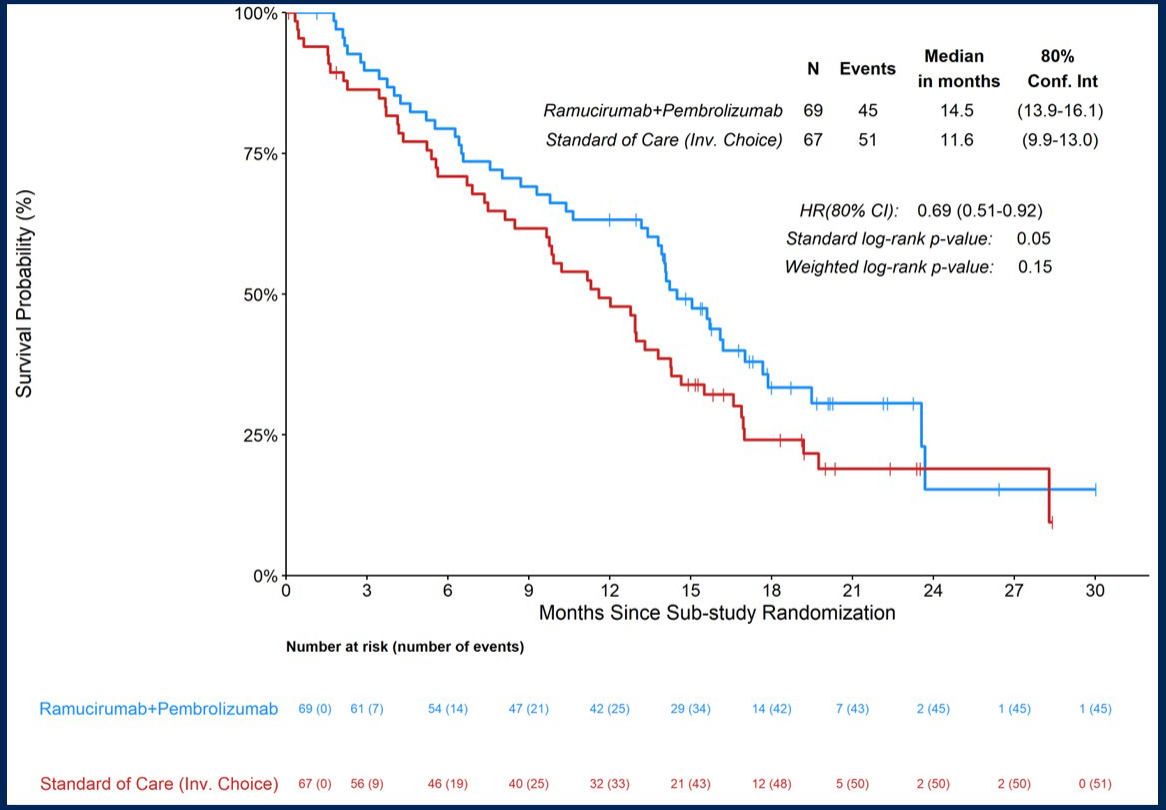
Primary endpoint: OS

Secondary endpoints: RR, DCR, DoR, PFS, Toxicities



Key eligibility: 1) Previously received both PD-1 or PD-L1 inhibitor therapy and platinum-based doublet chemotherapy either sequentially or combined, with PD on at least 84 days after initiation of ICI and platinum-based doublet therapy; 2) ECOG 0-1; 3) all patients met eligibility to receive ramucirumab

Overall survival



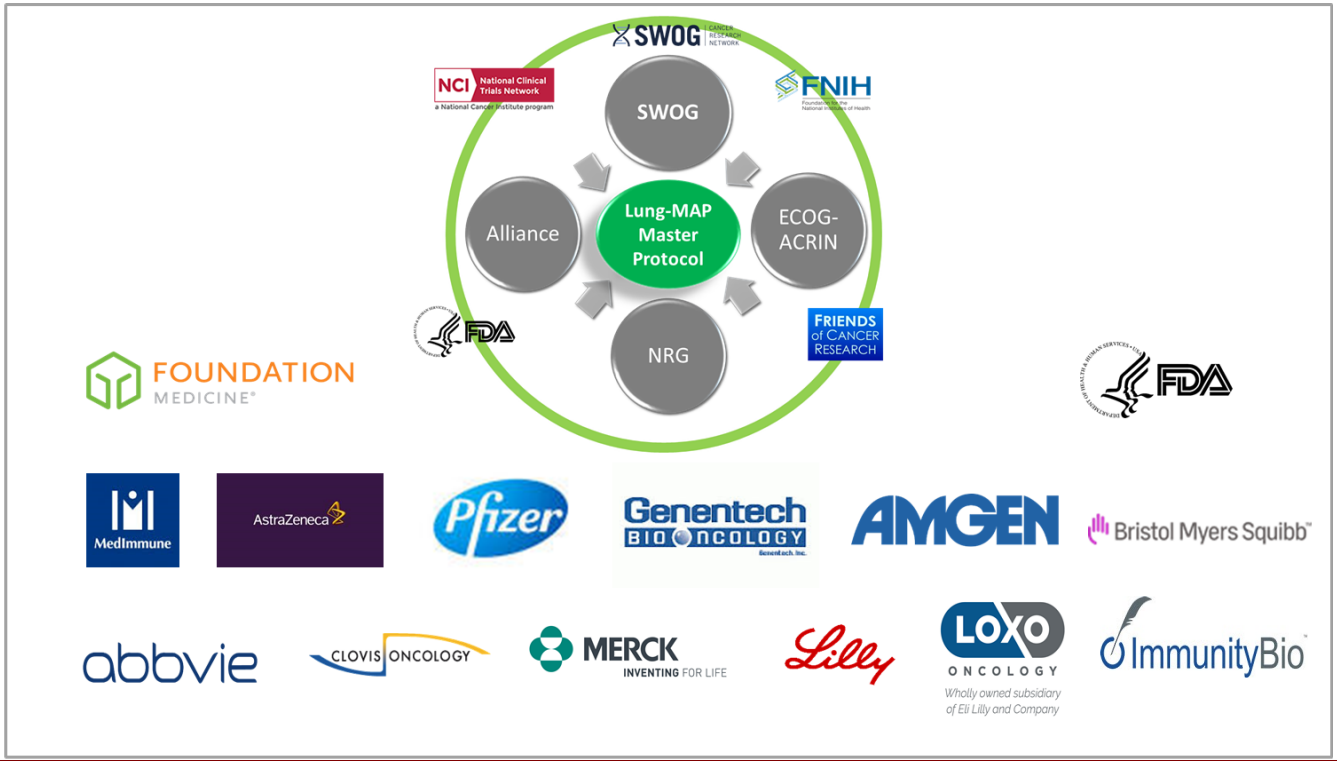
- Median OS for RP 14.5 months v. SOC 11.6 months
- HR= 0.69; SLR p-value 0.05

Standard of care therapy received:

- Docetaxel + Ramucirumab (n = 45)
- Docetaxel (n = 3)
- Gemcitabine (n = 12)
- Pemetrexed (n = 1)
- No treatment (n = 6)

Acknowledgements

Lung-MAP Partners and Collaborators



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Acknowledgements

Lung-MAP Impact

- Over 15 clinical trials following Lung-MAP blueprint
- FDA now has “master protocol” guidance and most pharma companies have launched a “master protocol”
- Over 4,000 registered patients at more than 900 sites
- Over 50 publications and abstracts
- Over 10,000 specimens in a public bank
- 300 genes identified with a genetic alteration

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

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

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