



**Lung-MAP S1400 Lung Master Protocol  
Update Meeting**

**Friday, April 29, 2016  
2:30 to 4:00 pm**

**Hyatt Regency San Francisco  
Seacliff A-D (Bay Level)**

**Agenda**

**Welcome**

**Karen Kelly, MD**  
SWOG Lung Committee Chair

**Study Updates**

**Vassiliki (Vali) Papadimitrakopoulou, MD**  
Study Chair, Medical Oncology

**S1400I Patient Reported Outcomes**

**Joseph Unger, PhD**  
Biostatistician, Patient Reported Outcomes

**Study Logistics**

**Mary Redman, PhD**  
Lead Biostatistician

**Tissue Requirements**

**Philip C. Mack, PhD**  
Study Co-Chair, Translational Medicine

**Quality Assurance and Monitoring**

**Elaine Armstrong, MS**  
SWOG Quality Assurance Manager

**Accrual Enhancement Committee**

**Roy Herbst, MD, PhD**  
Study Co-Chair, Medical Oncology

**Site Perspectives**

**Roy Herbst, MD, PhD**  
Study Co-Chair, Medical Oncology

**Emily Shardelow, BS, CCRP**  
Clinical Research Associate II  
Markey Cancer Center, University of Kentucky  
Lexington, Kentucky

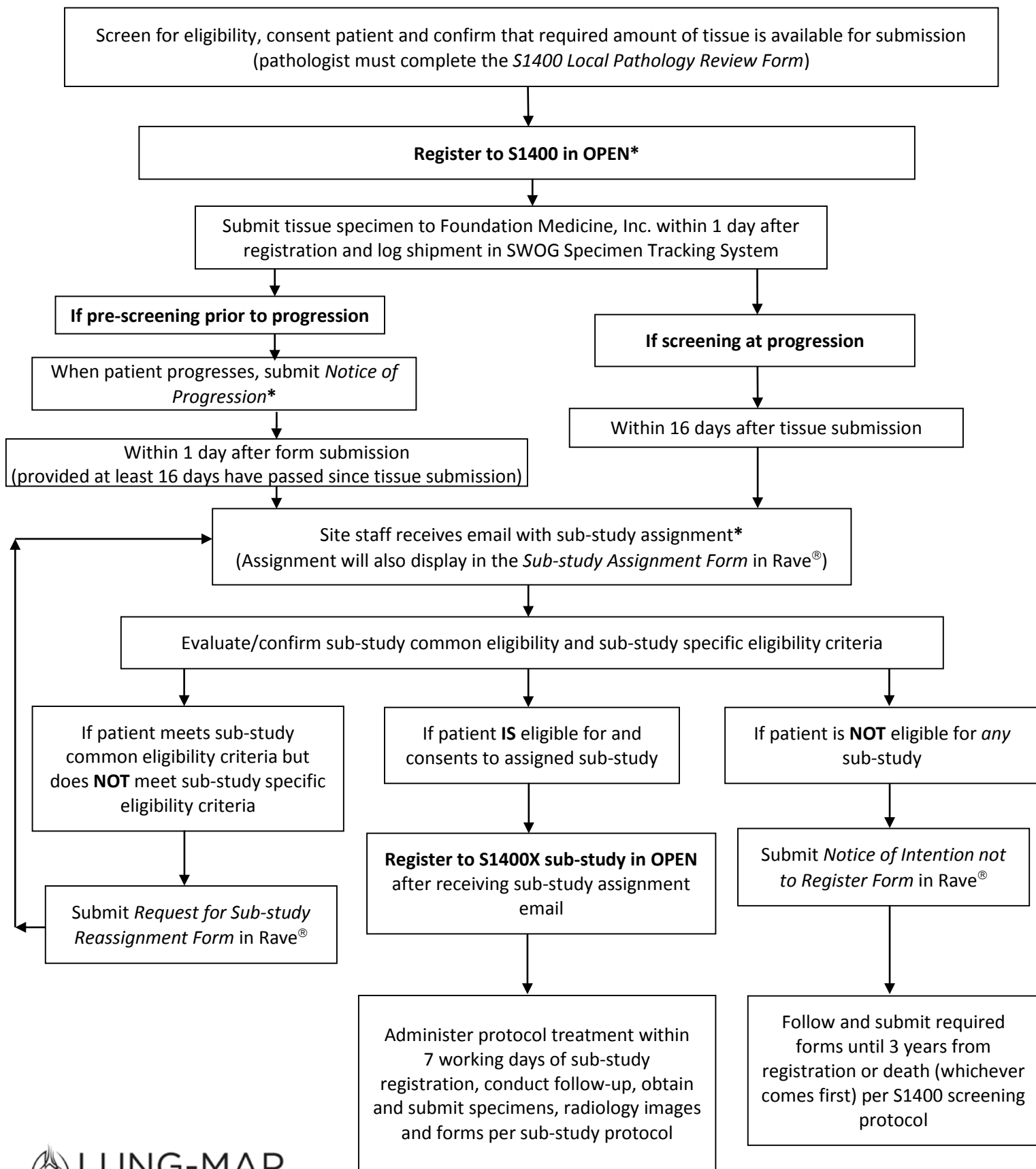
**James Wade, III, MD**  
Principal Investigator  
Heartland NCORP, Decatur, Illinois

**Questions and Answers**

**David Gandara, MD**  
Study Co-Chair, Moderator



## S1400 Registration and Study Flow



\*If it is determined that a patient will not register to a sub-study at any time following S1400 registration, the *Notice of Intention Not to Register* form must be submitted. Should the decision to not register a patient to their assigned sub-study be reversed, sub-study registration is allowed despite submission of the *Notice of Intention Not to Register* form.

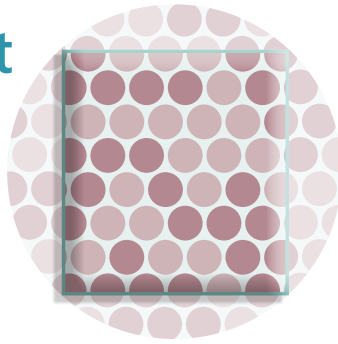


## Study requirement

### TUMOR CONTENT $\geq 20\%$

including tumor volume  $\geq 0.2 \text{ mm}^3$

It is important that the specimen contains as much tumor content as possible to ensure that there's enough DNA needed for sequencing.



**S1400 requires adequate tissue for biomarker profiling.**

For details, please refer to the **S1400** protocol Section 5 for eligibility requirements and Section 15 for a complete description of tissue requirements. Specimens must be submitted using the SWOG Specimen Tracking System, a process outlined in the **S1400** protocol Section 15.

**NOTE FOR LIVER SPECIMENS:**

**It is recommended that at least 40% of the specimen contain malignant cells to ensure sufficient tumor DNA.**

## For Best Results, Use These Specifications

### SPECIMEN TYPE

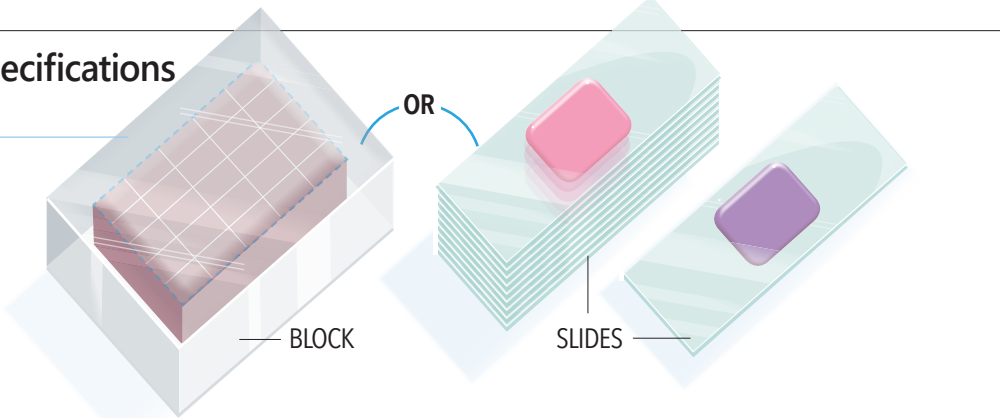
**FFPE BLOCK or 12-20 SLIDES (+H&E SLIDE)**

Tissue must be formalin-fixed and paraffin embedded. A tissue block is preferred.

**• If sending slides:**

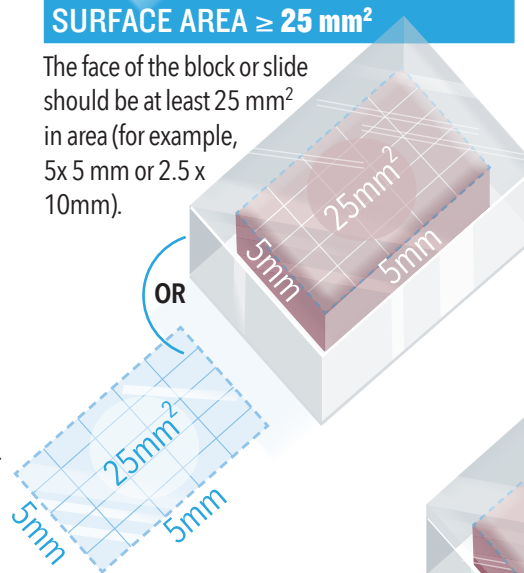
- A minimum of 12 unstained, charged, and unbaked 4-5 micron slides are required.
- 20 slides are highly recommended.
- Slides should include an additional H&E or Aperio stained slide (If unavailable, submit an extra unstained slide).

- **For core biopsy tissue**, use 3-5 cores embedded in a single block, aligned so that when cut, the blade is running parallel to the long axis of the cores.
- **Fine needle aspirates** with good cellularity are acceptable as long as cell blocks are established.
- **Biopsy tissue** can be from primary or metastatic sites. Bone biopsies are not allowed.



### SURFACE AREA $\geq 25 \text{ mm}^2$

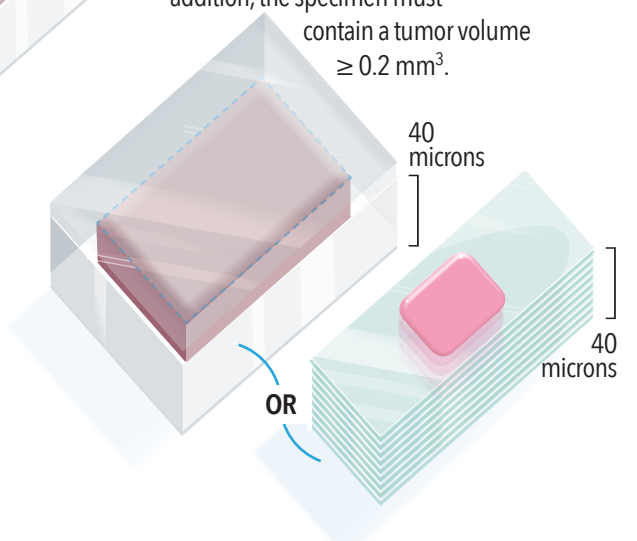
The face of the block or slide should be at least  $25 \text{ mm}^2$  in area (for example,  $5 \times 5 \text{ mm}$  or  $2.5 \times 10 \text{ mm}$ ).



### SPECIMEN VOLUME $\geq 1 \text{ mm}^3$

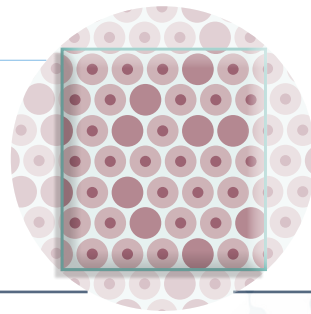
(including tumor volume  $\geq 0.2 \text{ mm}^3$ )

The total volume (surface area x depth) of the block or stacked slides should be at least  $1 \text{ mm}^3$ . If the surface area is  $25 \text{ mm}^2$  as recommended, the depth should be at least 40 microns. For this reason, a minimum of 12 slides is required. In addition, the specimen must contain a tumor volume  $\geq 0.2 \text{ mm}^3$ .



### NUCLEATED CELLULARITY $\geq 80\%$

Specimens containing less than 80% nucleated cells require greater total volume and may not be suitable to assay. A total of 75,000 to 150,000 nucleated cells are recommended.



**PRIOR TO ENROLLMENT, YOUR LOCAL PATHOLOGIST MUST SIGN OFF ON THE S1400 LOCAL PATHOLOGY REVIEW FORM CERTIFYING THAT TISSUE REQUIREMENTS HAVE BEEN MET.**

Questions? Email: [S1400question@crab.org](mailto:S1400question@crab.org)



# LUNG-MAP

## SITE COORDINATORS COMMITTEE



*We are seeking applicants for a new **S1400 Lung-MAP Site Coordinators Committee**. We would like the members to represent all types of sites: NCTN, NCORP, CCTG, academic, minority, etc. SWOG has funds to support travel for members to two SCC meetings per year, in conjunction with the SWOG Group Meeting, and funding for up to four conference calls per year. For more information about the committee and to apply:*

**<https://www.surveymonkey.com/r/LMAPSCC>**.

The committee will have representatives from across the Groups, minority sites, and broad geographic representation among participating sites. In addition to sharing in the planning, development and implementation of S1400 training and update meetings, the Committee members will be asked to recommend and review accrual enhancement strategies and materials, changes to study procedures, and updates to data collection forms. In addition, the SCC will provide content for a SCC column in the Lung-MAP staff newsletter and solicit feedback for other content. They will also advise the Accrual Enhancement Committee on content for the Lung-MAP website. Committee members will assist with study promotion and act as Lung-MAP representatives when attending Group meetings or other scientific meetings. Committee members may act as mentors or auditors, supporting the successful implementation of S1400 at the study sites.

1. The Site Coordinators Committee will be composed of 12 voting members.
2. The Committee officers will consist of a Chair, a Co-Chair and an Alternate Co-Chair, to be elected by the voting members of the Committee.
3. The SWOG Recruitment Manager and S1400 Lung-Map Project Manager will serve on the Committee as ex-officio non-voting members.
4. The Chair will provide meeting summaries to the S1400 leadership. The Chair may delegate this responsibility to another officer or member as necessary.
5. Members of the Site Coordinators Committee will serve for a minimum of a two year term. Terms are open-ended; members may continue to serve as long as they wish, provided they meet attendance and contribution criteria.
6. If a member resigns or is removed from the Committee, the Committee will solicit applications for membership and select a new member from those who apply. The Committee may also select a new member from a pool of applicants who applied for previous vacancies. The SWOG Statistical Center will maintain records of the application process.

**Application Deadline:  
May 15, 2016**



Ask Karen Anderson  
Recruitment & Adherence Manager  
[karena@crab.org](mailto:karena@crab.org)

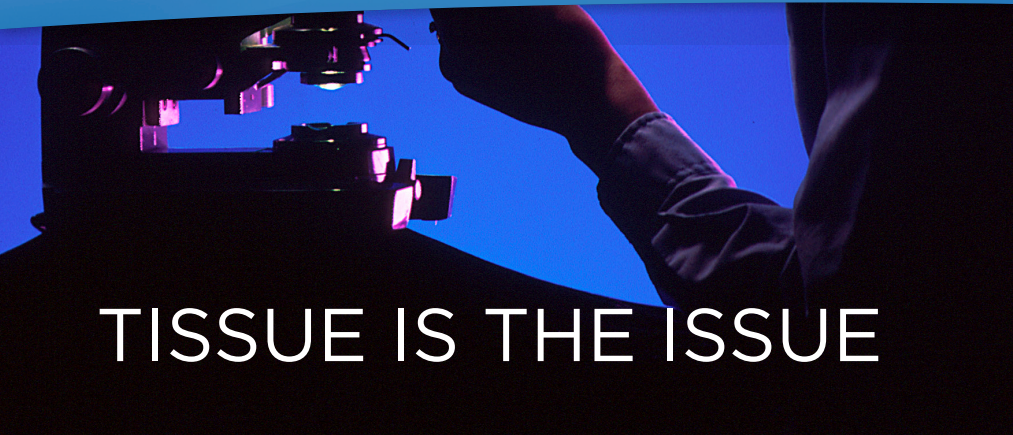


# LUNG-MAP

## FUNDING HIGHLIGHTS

- ❖ Sites will receive up to **\$5,869** (\$1,079 screening/ \$4,790 registration) for each patient on trial
- ❖ If biopsies are needed, sites will receive **\$3,000/\$6,000** for the biopsies performed at screening and/or progression after initial response on Arm1
- ❖ Sites will be reimbursed for additional research based procedures
- ❖ Sites will be reimbursed **\$1,333** for on-site visits outside the regular audit schedule

Funding Questions:  
SWOG Group Chair's Office, [funding@swog.org](mailto:funding@swog.org)  
For additional information, see funding memos



## TISSUE IS THE ISSUE

Securing and sending an adequate tumor tissue sample is essential to getting your patients quick access to treatment on the Lung-MAP trial. According to Dr. Fred Hirsch, Pathology Study Chair, “there must be local quality control at every step: acquisition, processing and submitting the tissue, to get good quality.”

One of the most important steps for success is confirmation by your local pathologist that the tissue sample meets the Lung-MAP specifications. The pathologist must review each sample before patients are registered to the Lung-MAP trial in order to meet protocol eligibility requirements. After registering the patient, the tissue then needs to be submitted as soon as possible so as not to delay the sub-study assignment. If a patient has already had biomarker testing at Foundation Medicine, the previous results cannot be used. Because of the potential use of these trials in FDA registration, the biomarker profiling must be done specifically for S1400.

Naomi L. Hullinger, RN, Supervisor, San Antonio Military Medical Center, credits their success to these 3 steps:

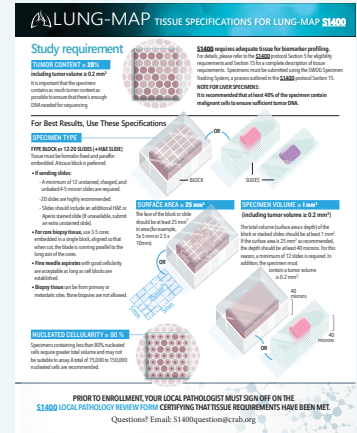
- 1) meeting with the Chief of Pathology to review the tissue requirements and timeline, discuss barriers and resolutions,
- 2) identifying a pathology staff member to work with, and
- 3) checking the status of available tissue as soon as a potential patient is identified.

## Tissue Specifications

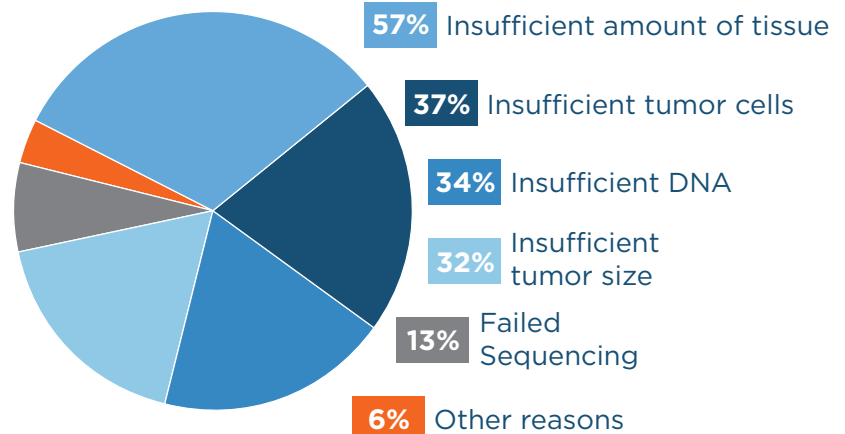
Tissue is most often inadequate for biomarker profiling due to insufficient tumor cells, DNA, or amount of tissue. For this reason, it is crucial that your local pathologist review the tissue for adequacy before submitting it to FMI. We

provide additional specimen collection and selection guidelines in the “Tissue Specifications for Lung-MAP S1400” document (shown above) to help ensure the best possible results.

The “Tissue Specifications for Lung-MAP S1400” document is available via CTSU.



## About 14% of tissue submissions are determined to be inadequate for:



(Note: a sample could have multiple reasons for inadequacy.)

Data as of March 11, 2016

HAVE A STORY IDEA FOR THIS NEWSLETTER?  
Contact Wendy Lawton at [lawtonw@ohsu.edu](mailto:lawtonw@ohsu.edu)



## The Top 12 Accruing Sites

Site	S1400 Accrual
Heartland Cancer Research NCORP	27
Kaiser Permanente NCI Community Oncology Research Program	20
Georgia NCI Community Oncology Research Program	19
Southeast Clinical Oncology Research (SCOR) Consortium NCORP	19
Catholic Health Initiatives NCORP	14
Yale University - Yale Cancer Center LAPS	13
Metro Minnesota Community Oncology Research Consortium	13
University of Pittsburgh Cancer Institute LAPS	12
Michigan Cancer Research Consortium NCORP	12
VCU Massey Cancer Center Minority Underserved NCORP	12
Wisconsin NCI Community Oncology Research Program	11
Wichita NCI Community Oncology Research Program	10

### All site representatives are invited!

Lung-MAP Update Meeting

SWOG Group Meeting

San Francisco Hyatt Regency

Friday, April 29

2:30 pm - 4:00 pm PST

Register for this meeting at [swog.org](http://swog.org)

### Did you know?

- If archival tissue is not sufficient, funding is available for an S1400 screening biopsy. Logging the tissue into SWOG Specimen Tracking will trigger reimbursement. If the patient has a biopsy specifically for the trial but is never registered, you can email [funding@swog.org](mailto:funding@swog.org) for a reimbursement form.
- For pre-screening patients: Submission of the S1400 Notice of Progression is required to receive the patient's substudy assignment and full biomarker report. The assignment email will be sent one day after submission of this form, provided at least 16 days have passed since tissue submission.
- The study's biomarker profiling includes EGFR and ALK testing. It is not required prior to S1400 registration, but if testing was done, the patient must not have been positive for either of these alterations

## STUDY CONTACTS GOT A LUNG-MAP QUESTION? HERE'S WHO TO CALL.

### Eligibility + Imaging + Data Submission:

Data Operations, (206) 652-2267  
[S1400Question@crab.org](mailto:S1400Question@crab.org)

### Protocol + Regulatory:

SWOG Operations Office,  
(210) 614-8808, ext. 1019  
[cmiwa@swog.org](mailto:cmiwa@swog.org)

### Treatment + Toxicity Study Distribution

#### Lists:

S1400A: [S1400AMedicalQuery@swog.org](mailto:S1400AMedicalQuery@swog.org)  
S1400B: [S1400BMedicalQuery@swog.org](mailto:S1400BMedicalQuery@swog.org)  
S1400C: [S1400CMedicalQuery@swog.org](mailto:S1400CMedicalQuery@swog.org)  
S1400D: [S1400DMedicalQuery@swog.org](mailto:S1400DMedicalQuery@swog.org)  
S1400I: [S1400IMedicalQuery@swog.org](mailto:S1400IMedicalQuery@swog.org)

### Funding Questions:

Group Chair's Office,  
[funding@swog.org](mailto:funding@swog.org)  
For additional information,  
see funding memos.





# LUNG-MAP

## WHO DO I ASK...? CONTACT LIST

Eligibility / Data Submission	Protocol / Regulatory	Public Relations / Media
Louise Highleyman and Kara Amber Data Coordinators SWOG Data Operations Center (206) 652-2267 <a href="mailto:S1400Question@crab.org">S1400Question@crab.org</a>	Crystal Miwa Protocol Coordinator SWOG Operations Office (210) 614-8808 ext 1019 <a href="mailto:cmiwa@swog.org">cmiwa@swog.org</a>	Wendy Lawton SWOG Communications Manager SWOG Group Chair's Office (503) 348-8675 <a href="mailto:lawtonw@ohsu.edu">lawtonw@ohsu.edu</a>
Specimen	Imaging	
Fred R. Hirsch, MD, PhD Study Co-Chair (303) 724-3858 <a href="mailto:fred.hirsch@ucdenver.edu">fred.hirsch@ucdenver.edu</a>	Philip C. Mack, PhD Study Co-Chair (916) 734-8022 <a href="mailto:pcmack@ucdavis.edu">pcmack@ucdavis.edu</a>	Lawrence H. Schwartz, MD Study Co-Chair (212) 305-8994 <a href="mailto:lschwartz@columbia.edu">lschwartz@columbia.edu</a>
Specimen and Imaging Submission		
Foundation Medicine Inc. (617) 418-2200 <a href="mailto:S1400@foundationmedicine.com">S1400@foundationmedicine.com</a>	TRIAD <a href="mailto:SWOG1400@irocohoio.org">SWOG1400@irocohoio.org</a> or call IROC Ohio at 614-293-2929	
USA Investigational Drug Distribution		
Pharmaceutical Management Branch (PMB) Matthew Boron (240) 276-6575 <a href="mailto:PMBAfterHours@mail.nih.gov">PMBAfterHours@mail.nih.gov</a>		
Funding		
<b>Federal funding:</b> Pat Mize, MBA Accounting Specialist (503) 418-4533 <a href="mailto:mizep@ohsu.edu">mizep@ohsu.edu</a>	<b>Non-federal funding:</b> Casey Dawson Financial Administration: SWOG-CTI (734) 998-6889 <a href="mailto:casey@thehopefoundation.org">casey@thehopefoundation.org</a>	



# LUNG-MAP

## WHO DO I ASK...? CONTACT LIST

### **S1400 Treatment-related/Medical**

Vassiliki Papadimitrakopoulou, MD  
Study Chair  
(713) 792-6363  
[S1400MedicalQuery@swog.org](mailto:S1400MedicalQuery@swog.org)

Roy S. Herbst, MD  
Study Co-Chair  
(203) 785-6879  
[S1400MedicalQuery@swog.org](mailto:S1400MedicalQuery@swog.org)

David R. Gandara, MD  
Study Co-Chair  
(916) 734-3771  
[S1400MedicalQuery@swog.org](mailto:S1400MedicalQuery@swog.org)

### **Sub-Study Treatment-related/ Medical**

#### **Study Chair**

#### **Study Co-Chair**

#### **S1400A**

[S1400AMedicalQuery@swog.org](mailto:S1400AMedicalQuery@swog.org)

Vassiliki A. Papadimitrakopoulou, MD  
NCTN Group: SWOG  
(713) 792-6363

Hossein Borghaei, DO  
NCTN Group: ECOG-ACRIN  
(215) 214-4297

#### **S1400B**

[S1400BMedicalQuery@swog.org](mailto:S1400BMedicalQuery@swog.org)

Corey J. Langer, MD  
NCTN Group: NRG  
(215) 615-5121

Jeffrey A. Engelman, MD, PhD  
NCTN Group: ALLIANCE  
(617) 724-4000

#### **S1400C**

[S1400CMedicalQuery@swog.org](mailto:S1400CMedicalQuery@swog.org)

Martin J. Edelman, MD  
NCTN Group: ALLIANCE  
(410) 328-8708

Kathy S. Albain, MD  
NCTN Group: SWOG  
(708) 327-3102

#### **S1400D**

[S1400DMedicalQuery@swog.org](mailto:S1400DMedicalQuery@swog.org)

Charu Aggarwal, MD, MPH  
NCTN Group: ECOG-ACRIN  
(215) 662-6318

Primo N. Lara, Jr., MD  
NCTN Group: SWOG  
(916) 734-5959

#### **S1400E**

[S1400EMedicalQuery@swog.org](mailto:S1400EMedicalQuery@swog.org)

Mark A. Socinski, MD  
NCTN Group: ALLIANCE  
(412) 692-4724

#### **S1400I**

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Lyudmila A. Bazhenova, M.D.  
NCTN Group: Alliance  
(858) 822-6189