



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

**Friday, September 16, 2016
2:15 to 3:45 pm**

**Hyatt Regency Chicago
Regency D (West Tower, Gold Level)**

Agenda

Welcome

Karen Kelly, MD

SWOG Lung Committee Chair

Study Updates

Vassiliki (Vali) Papadimitrakopoulou, MD

Study Chair, Medical Oncology

**Study Logistics /
S1400I Patient Reported Outcomes**

Mary Redman, PhD

Lead Biostatistician

Quality Assurance and Monitoring

Elaine Armstrong, MS

SWOG Quality Assurance Manager

Accrual Enhancement Committee

Roy Herbst, MD, PhD

Study Co-Chair, Medical Oncology

Site Coordinators Committee

Jessica Jordan, BA

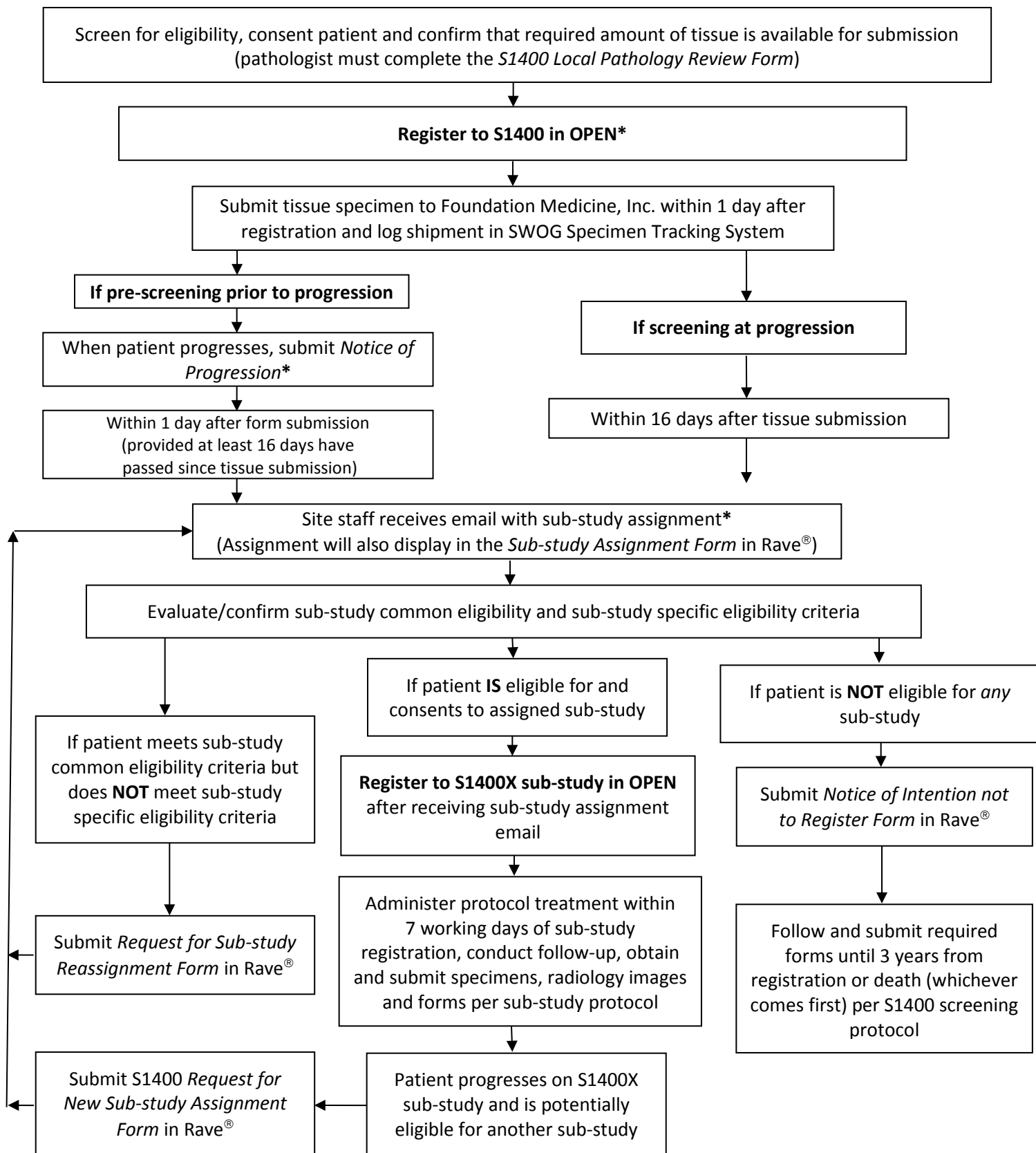
Site Coordinator Committee Chair

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.

The Lung-MAP Site Coordinator Committee (SCC) was formed in July 2016. The members are site staff from a variety of institutions, NCTN affiliations, and geographical locations who work closely with the study leadership. The members provide recommendations and feedback on accrual strategies, patient and promotional materials, changes to study procedures, data collection, and staff training materials. Look for their face or name on their badge and let them know your concerns, questions, or helpful advice for making Lung-MAP collaborative and successful. You can also contact them at LungmapSCC@crab.org.



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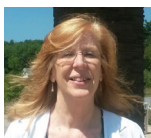
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Veteran's Affairs Connecticut /
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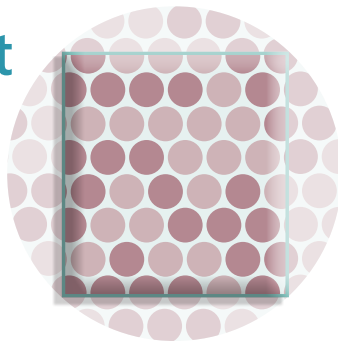


Study requirement

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

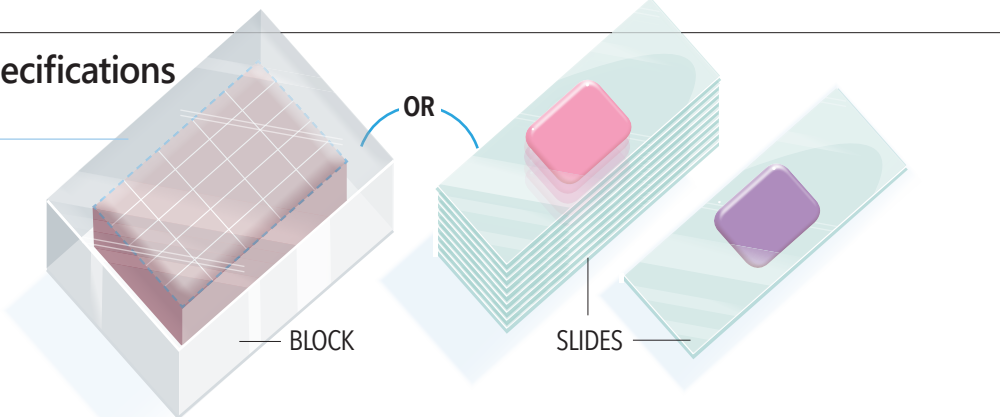
FFPE BLOCK or 12-20 SLIDES (+H&E SLIDE)

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

• If sending slides:

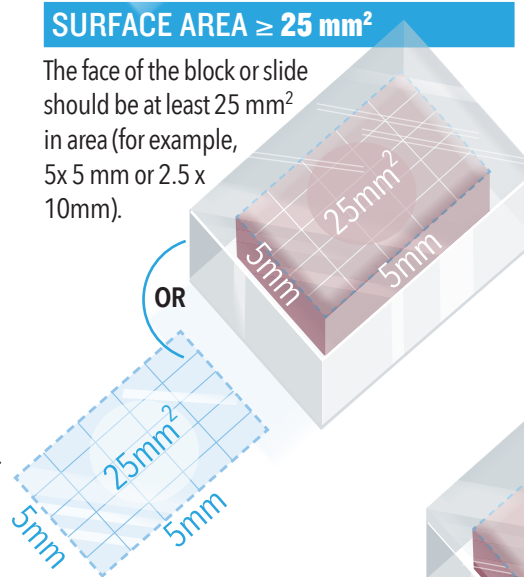
- A minimum of 12 unstained, charged, and unbaked 4-5 micron slides are required.
- 20 slides are highly recommended.
- Slides should include an additional H&E or Aperio stained slide (If unavailable, submit an extra unstained slide).

- **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 $\geq 25 \text{ mm}^2$

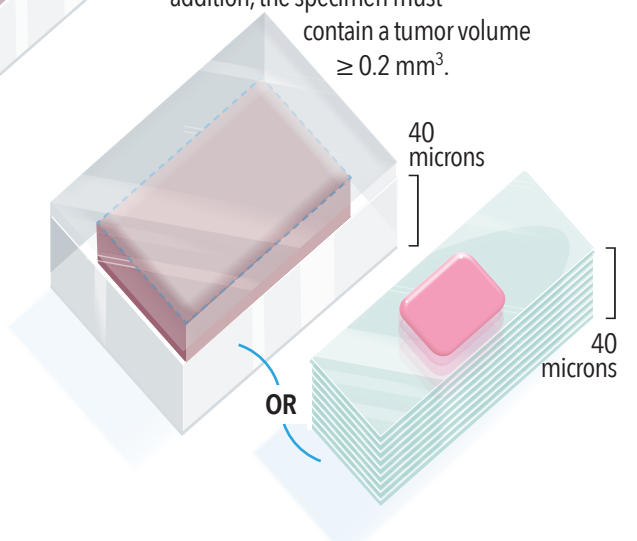
The face of the block or slide should be at least 25 mm^2 in area (for example, $5 \times 5 \text{ mm}$ or $2.5 \times 10 \text{ mm}$).



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

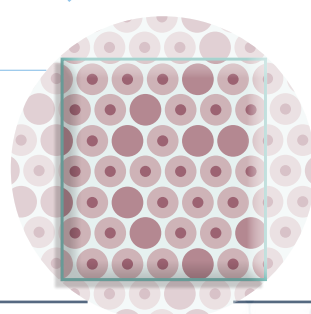
(including tumor volume $\geq 0.2 \text{ mm}^3$)

The total volume (surface area x depth) of the block or stacked slides should be at least 1 mm^3 . If the surface area is 25 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



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FUNDING HIGHLIGHTS

- ❖ Sites will receive up to **\$5,869** (\$1,079 screening/ \$4,790 registration) for each patient on trial
 - Additional Site Payment for patients registered to **\$1400** of **\$500** for a limited duration.
- ❖ 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
For additional information, see funding memos



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WHO DO I ASK...? CONTACT LIST

Eligibility / Data Submission	Protocol / Regulatory	Public Relations / Media
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Specimen and Imaging Submission		
Foundation Medicine Inc. (617) 418-2200 S1400@foundationmedicine.com	TRIAD SWOG1400@irocohoio.org or call IROC Ohio at 614-293-2929	
USA Investigational Drug Distribution		
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Funding		
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