



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

**Friday, April 13, 2018
2:30 to 4:00 pm**

**Hyatt Regency San Francisco
Bay Level, Seacliff Room**

Agenda

Welcome

David Gandara, MD

S1400 Study Co-Chair

Study Updates

Vassiliki (Vali) Papadimitrakopoulou, MD

S1400 Study Chair, Medical Oncology

S1400F Overview

Mary Redman, PhD

S1400 Lead Biostatistician

S1400GEN Overview

Joshua Roth, PhD, MHA

S1400GEN Study Chair

S1400K Overview

Saiama Waqar, MBBS, MSCI

S1400K Study Chair

Future Studies

Roy Herbst, MD, PhD

S1400 Study Co-Chair

Screening ctDNA

Philip Mack, PhD

S1400 Translational Medicine Chair

Site Coordinators Committee

Lavinia Dobrea RN, MS, OCN

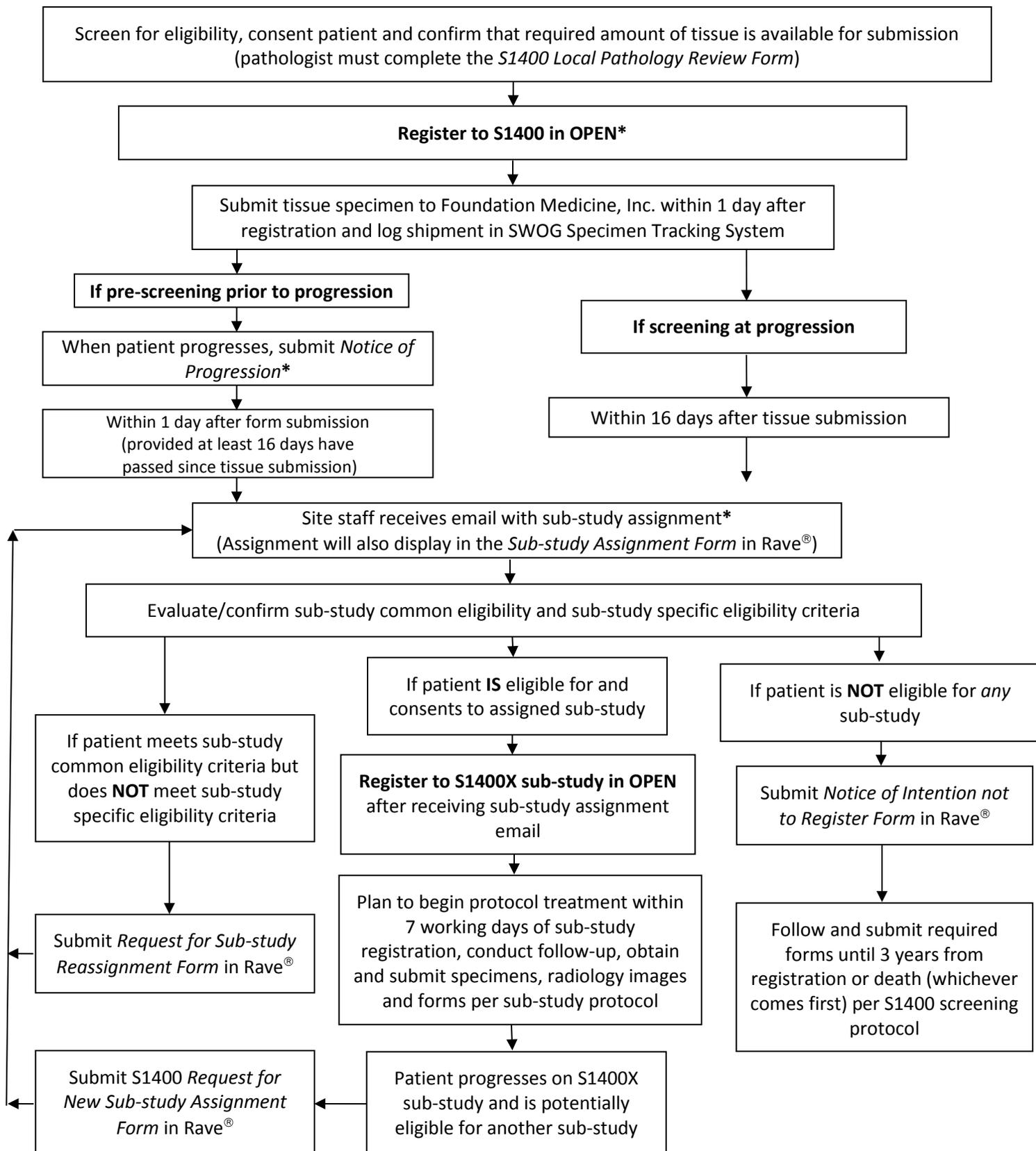
Site Coordinator Committee Co-Chair

Q & A Session

David Gandara, MD

S1400 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.

LUNG-MAP S1400 Site Coordinator Committee

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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SWOG



TBD

CCTG



TBD



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S1400GEN Ancillary Study

Overview – S1400GEN Activated 2/5/18

- Sites provide patients a hard copy of the Patient Survey with Cover Letter at time of consent to allow them to follow along during phone interview.
- Sites complete “For Site Use Only” box on 2nd page of S1400GEN Consent. Use the treating investigator email address (not the Study PI) and fax that page to **866-332-1593** within 7 days of registration. Site involvement ends here. Fred Hutch contacts patients, implements survey, and sends thank you with gift cards.
- **Physician Survey:** Fred Hutch will approach, consent, and send online physician survey link to treating physicians.
- See S1400 Section 15.5 and Section 18.1f for staff instructions.

Where to Find S1400GEN Documents

- Surveys and Cover Letter can be found on the CTSU Website (<https://www.ctsu.org>) under S1400 > CIRB Documents > Amendment Reviews
 - Cover Letter: Participant Survey Cover Letter > Support Documents
 - Survey: Scroll down to Revision 12 > Support Documents
- If having trouble, contact Crystal Miwa (cmiwa@swog.org)

Frequently Asked Questions	
Where is the S1400GEN Patient Consent?	In S1400 Screening and Pre-Screening Consent Forms, listed as #3 Optional Research Survey Study.
Can sites opt out of any part of S1400GEN?	S1400GEN must be <u>offered</u> to S1400 patients and physicians.
Do sites need to consent Physicians?	Physician Consent was provided for reference only. Fred Hutch consents physicians.
Should sites insert their info for Patient Consent IRB Contact Info?	Please leave as Fred Hutch staff and IRB contact info.
Can sites opt out of gift cards?	No. Fred Hutch will buy and send gift cards.
Can sites delete bracketed language in protocol about patient online survey?	Bracketed language must be kept. This was intended to be included for an easy switch from the survey being conducted via phone to online.

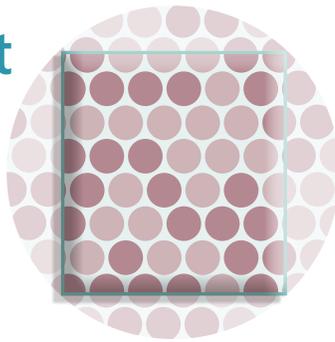


Study requirement

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

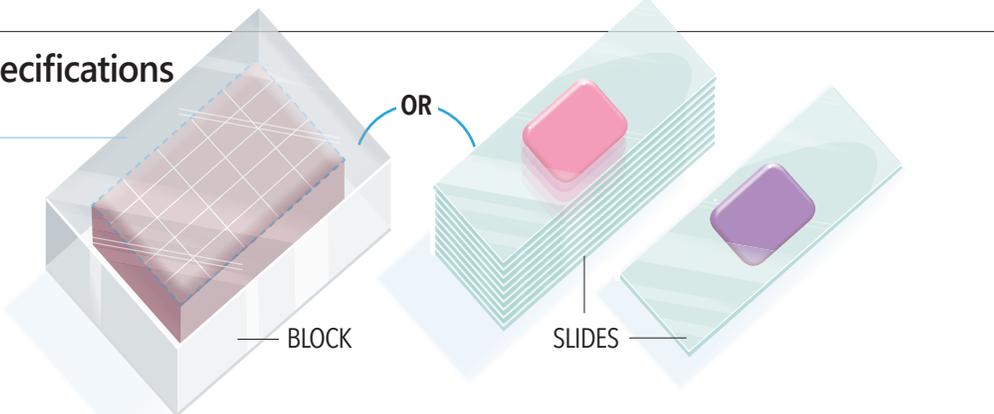
FFPE BLOCK or 12-20 SLIDES (+H&E SLIDE)

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

• If sending slides:

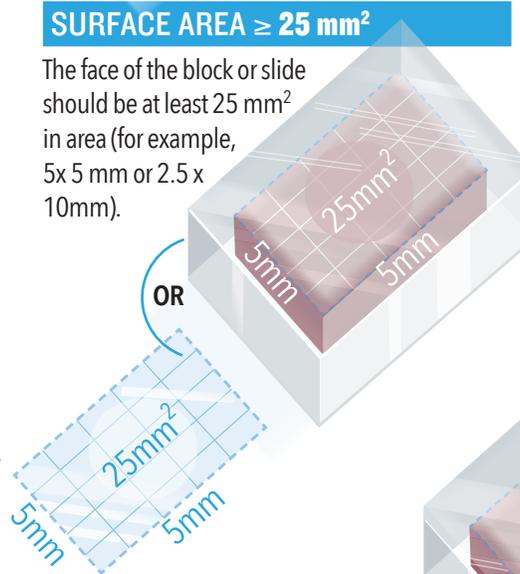
- A minimum of 12 unstained, charged, and unbaked 4-5 micron slides are required.
- 20 slides are highly recommended.
- Slides should include an additional H&E or Aperio stained slide (If unavailable, submit an extra unstained slide).

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

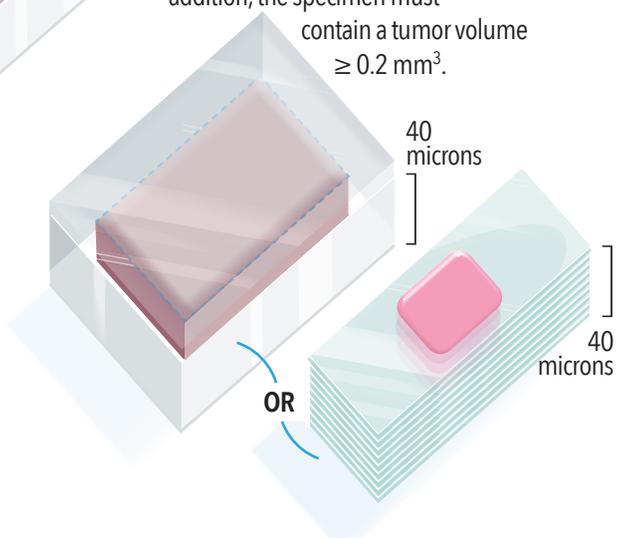
The face of the block or slide should be at least 25 mm^2 in area (for example, $5 \times 5 \text{ mm}$ or $2.5 \times 10 \text{ mm}$).



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

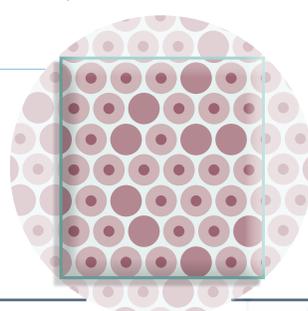
(including tumor volume $\geq 0.2 \text{ mm}^3$)

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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WHO DO I ASK...? CONTACT LIST

Eligibility / Data Submission	Protocol / Regulatory	Public Relations / Media
Louise Highleyman and Krystle Pagarigan Data Coordinators SWOG Data Operations Center (206) 652-2267 S1400Question@crab.org	Crystal Miwa and Mariah Norman Protocol Coordinators SWOG Operations Office (210) 614-8808 cmiwa@swog.org mnorman@swog.org	Wendy Lawton SWOG Communications Manager SWOG Group Chair's Office (503) 348-8675 lawtonw@ohsu.edu
Specimen	Imaging	
Fred R. Hirsch, MD, PhD Study Co-Chair (303) 724-3858 fred.hirsch@iaslc.org	Philip C. Mack, PhD Study Co-Chair (916) 734-8022 pcmack@ucdavis.edu	Lawrence H. Schwartz, MD Study Co-Chair (212) 305-8994 lhs2120@cumc.columbia.edu
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		
Pharmaceutical Management Branch (PMB) Matthew Boron (240) 276-6575 PMBAfterHours@mail.nih.gov		
Funding		
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Sub-Study Treatment-related/ Medical

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