



## Lung-MAP Trial Expansion FAQ

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### *CIRB Questions*

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**Do we need to make separate submissions to the CIRB to open each LUNGMAP sub-study at our site?**

Yes. The new study structure considers the studies as standalone trials for regulatory purposes. A separate Study-Specific Worksheet (SSW) is required for each of the studies: **LUNGMAP**, **S1900A**, and for each new sub-study going forward.

**Should we submit a Study Specific Worksheet as soon as each new LUNGMAP sub-study is activated?**

The CIRB is allowing sites to either submit a Study Specific Worksheet (SSW) as soon as a study is activated or wait to submit an SSW until a patient is assigned to that sub-study. Although the choice is up to the site, it is recommended to open sub-studies as soon as a study is activated to reduce delay of registering a patient. Regardless of the choice made, it is the responsibility of the sites to utilize the most current version of the protocol and consent.

**If our site already has S1400 open with the NCI CIRB and we want to open LUNGMAP, do we have to open LUNGMAP and the new sub-studies (i.e., S1900A) with the CIRB?**

Yes. The **LUNGMAP** screening protocol is a new study. The new study structure considers each new sub-study a standalone trial, requiring separate CIRB applications.

**For sites that already have S1400 opened, can we keep S1400F open under our local IRB or transfer S1400F to CIRB?**

Yes. **S1400** and **S1400F** can remain open under local IRB or be transferred to the NCI CIRB. This is up to the site. The new **LUNGMAP** screening protocol and any new sub-study must be opened under the CIRB.

**For sites that already have S1400 open, can the S1400 screening protocol remain under local IRB and the LUNGMAP screening protocol be under the NCI CIRB?**

Yes. **LUNGMAP** is separate from **S1400** and they can be opened under separate IRBs.



**Will the different studies have different IRB numbers?**

The CIRB does not use unique IRB numbers. The CIRB utilizes the Group's study number or naming convention, such as **S1900A**.

**Will there be separate CIRB approval dates for the new LUNGMAP screening protocol and sub-studies?**

There is potential for separate approval dates for each study as each study can be reviewed and approved separately by the CIRB.

**Will the continuing review be separate for the screening protocol and each sub-study?**

No. **LUNGMAP** and its sub-studies are conducted under a single IND and should be processed as a single study for continuing review. The CIRB conducts one continuing review and the entire study including **LUNGMAP** and its associated sub-studies will have one expiration date. This allows the CIRB to review the study as a whole. Any sub-study, regardless of when it was approved, will use the CIRB's expiration date from the main study.

**How will amendments be handled by the CIRB?**

There will be separate amendments for the **LUNGMAP** screening protocol and each sub-study. However, because Lung-MAP is an umbrella protocol, the **LUNGMAP** screening protocol and its sub-studies will be processed as a single study for continuing review purposes.



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## *Training Requirements*

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### **What are the training requirements?**

Per the protocol, one member of each institution (CRA or investigator, etc.) must complete the Protocol Specific Requirements (PSR) prior to patient registration. The PSR will need to be renewed prior to patient registration each time a new sub-study has been added.

The PSR can be satisfied by completing the training online and submitting the verification at: <https://www.swog.org/required-lung-map-s1400-training>.

To receive credit, submit a saved copy or printout of the training verification form via the CTSU Regulatory Submission Portal. The research staff member who completes the training can include all the CTEP ID codes they are associated with. For example, a head site may include the CTEP ID codes from the multiple satellite sites in the training verification form. The SWOG Protocol Coordinator and CTSU will be notified of completion.

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## *Opening Sub-Studies at the Site*

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### **Is it required to open all LUNGMAP sub-studies?**

No. Sites do not have to participate in all sub-studies. However, it is strongly advised to do so, in order to provide patients as many treatment options as possible.

### **Does S1400 need to be open with our IRB of record before we can open LUNGMAP?**

Although it is not required to have S1400 open at your site before opening LUNGMAP, if you would like to register a patient to S1400F, you would need S1400 and S1400F open at your site. If your site is opening S1400 and S1400F for the first time, they must be opened with the CIRB. Opening S1400F requires the submission of a single SSW for S1400.

### **Does the new LUNGMAP screening protocol need to be open at our site in order for patients on S1400 to be registered to the new LUNGMAP sub-studies (i.e., S1900A)?**

Yes. The LUNGMAP screening protocol must be open at the site for regulatory purposes before patients on S1400 can be registered to the new sub-studies. Please note that S1400 patients do not have to re-screen on the LUNGMAP screening protocol.



**Does the S1400 screening protocol and S1400F sub-study need to be open at our site in order for patients on LUNGMAP to be registered to S1400F?**

Yes. Both the S1400 screening protocol and S1400F sub-study must remain open in order for patients from LUNGMAP to be registered onto S1400F. Sites that did not previously have S1400 open must open S1400, S1400F and LUNGMAP for a patient to be registered to S1400F.

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*Closing S1400 with the IRB*

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**Can we close S1400 out with our IRB of record?**

We anticipate that most sites will not close S1400 at their IRB at this time. Please contact [S1400question@crab.org](mailto:S1400question@crab.org) to verify all required items have been met before closing S1400 at your IRB.

- Sites that registered patients to S1400 should keep S1400 open with your IRB of record until all patients have completed follow-up and all data entry queries and expectations have been resolved. In addition, if any S1400 patients registered to a sub-study, S1400 should remain open at the IRB until the definitive manuscript(s) for those sub-studies have been published. S1400 would also need to remain open so eligible patients may be registered to S1400F after screening on the LUNGMAP screening protocol.
- Sites that never registered patients to S1400 but want to register eligible patients to S1400F will need to open the LUNGMAP screening protocol as well as keep S1400 open at their site.
- Sites that never registered patients to S1400 and do not intend to open LUNGMAP may close S1400 with their IRB of record.



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*Eligibility and Data Submission Questions*

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**Can patients screened on S1400 be assigned to LUNGMAP sub-studies? Can patients screened on LUNGMAP be assigned to S1400F?**

Yes. Patients who screened on S1400 may potentially be assigned to LUNGMAP sub-studies (i.e., S1900A) and patients who screen on LUNGMAP may be assigned to S1400F if eligible.

**If patients have archival tissue, do they need to be registered to Step 0?**

No. If a patient has adequate archival tissue available for submission to the study, register the patient directly to Step 1.

Step 0 is an administrative “pre-registration” step to provide a SWOG patient ID number for submission of whole blood for the ctDNA research assay. This blood collection is required only for those patients who will undergo a fresh biopsy to obtain tissue for the study.

**If a patient has previously had Foundation Medicine testing done, can these results be used to enroll a patient on a sub-study?**

If the Foundation Medicine testing was done outside of the Lung-MAP study, it cannot be used for sub-study assignment at this time. The patient must be registered to the LUNGMAP screening protocol and tissue must be submitted through the study.

If the patient was registered to S1400 and tissue testing was performed through the study, the patient should not be re-registered to LUNGMAP and will not need to submit additional tissue. We will do our best to assess all previously registered patients (on S1400 as well as LUNGMAP) for the biomarkers involved in any new sub-studies that open up. This may depend on the specific sub-study and biomarkers involved.

**If we are not able to activate a sub-study at the time a patient is assigned (i.e., logistical issues with pharmacy), can the patient be assigned to a different sub-study?**

Yes. Please complete the Request for Sub-Study Reassignment form located in Rave in the patient’s screening study (S1400 or LUNGMAP). Please note that once re-assigned, patients cannot be assigned back to a sub-study to which they were previously assigned. Please use this option only when necessary. See timing between assignment and registration below.



### **What is the timing between sub-study assignment and registration?**

There is no time limit between when the patient receives sub-study assignment and when they can be registered to the sub-study, as long as the patient meets eligibility requirements at the time of registration, and the sub-study remains open to accrual.

### **Can starter kits for the ctDNA testing be requested in advance?**

No; however, please note that a patient ID number is not required to order a kit. If a patient has been identified as needing a fresh biopsy and has signed consent, then the ctDNA kit can be requested. Please allow 3 days for receipt of kit.

### **Can specimens be shipped on Fridays?**

Yes. Please mark Friday shipments for next day delivery. FMI accepts Saturday deliveries.

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### *Contact Information*

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### **How can we contact the study team for questions?**

Eligibility or data submission questions – [LUNGMAPquestion@crab.org](mailto:LUNGMAPquestion@crab.org)

General protocol or regulatory questions – [mnorman@swog.org](mailto:mnorman@swog.org) or [srice@swog.org](mailto:srice@swog.org)

Treatment-related questions – [SXXXXXMedicalQuery@swog.org](mailto:SXXXXXMedicalQuery@swog.org) (i.e., [S1400FMedicalQuery@swog.org](mailto:S1400FMedicalQuery@swog.org), [S1900AMedicalQuery@swog.org](mailto:S1900AMedicalQuery@swog.org))

General medical questions about Lung-MAP overall – [LUNGMAP@swog.org](mailto:LUNGMAP@swog.org)

Funding questions – [Funding@swog.org](mailto:Funding@swog.org)

Site Coordinators Committee – [LUNGMAPSCC@crab.org](mailto:LUNGMAPSCC@crab.org)