

## ALCHEMIST FAQs: What Sites Need to Know

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### **1. Is ALCHEMIST one trial or three separate trials?**

The ALCHEMIST study is made up of three separate protocols: ALCHEMIST-screening (A151216), ALCHEMIST-EGFR (A081105), and ALCHEMIST-ALK (E4512). The first is a screening study which provides EGFR and ALK genotyping while the other two are treatment trials studying adjuvant targeted therapies.

### **2. Do I need to have all 3 trials open before I accrue patients?**

Yes, all the trials (A151216, A081105 and E4512) need to be IRB approved before patients are accrued to any of them. Sites will not be able to use the OPEN system to register patients to ALCHEMIST-screening until all 3 trials have been IRB approved. You can refer to the materials, include the activation notice, on the CTSU website which provides these instructions.

### **3. Can I just register patients to ALCHEMIST-screening (A151216) and not consider the treatment trials, or is the intent to register patients to the screening study in order to then put the eligible patients on the treatment trials?**

The intent of ALCHEMIST-screening is to screen patients for the treatment trials. Therefore, all patients registered to the screening study and found to be eligible for the treatment trials should be registered to the treatment trials.

### **4. I have a patient where we did local testing and the patient is negative for both ALK and EGFR. Is this patient eligible?**

Yes, patients are now eligible to be enrolled regardless of any local genotyping results as this was in Update #1 of ALCHEMIST-screening, issued on 3/15/15. These patients will still have tumor submitted for analysis to Response Genetics. If positive for EGFR or ALK on the screening study, they then would be potentially eligible for the treatment trials.

### **5. Is there a timeframe I need to follow to register post-op patients to this trial?**

Yes, the timeline for ALCHEMIST-screening is intended to allow sufficient time for genotyping so that patients will remain potentially eligible for the treatment trials. Patients that do not receive adjuvant therapy need to be registered the screening study up to 75 days following surgery, those patients that are receiving adjuvant therapy are to be registered up to 165 days after surgery, and those patients receiving both adjuvant chemotherapy and radiation therapy are to be registered up to 225 days following surgery.

## **6. Can patients be receiving adjuvant therapy while being registered to ALCHEMIST?**

Yes, patients can be receiving adjuvant therapy while being registered to ALCHEMIST-screening.

## **7. I don't understand the pre-registration and registration steps?**

The pre-registration step was developed to allow flexibility so that patients can be consented to ALCHEMIST-screening either prior to surgery or after surgery. All patients must pre-register first. Those that have already undergone surgery will then immediately proceed to registration to the study. However, pre-operative patients will first need to complete surgery to allow a final eligibility review prior to registering to the screening study.

## **8. When do I send in the tissue to Response Genetics? When do I collect and send in the blood?**

Tissue is sent to Response Genetics for genotyping after the patient is registered. Blood can be collected at any point following pre-registration up until 30 days after registration. Once collected the blood is to be shipped to the NCI BCR within 1 week of collection.

## **9. If my patient is locally EGFR or ALK positive, do I need to send in a block?**

Yes, patients who are locally positive for EGFR or ALK still need to send in tissue and blood. The tissue is used for confirmation of the genotype, and the tissue and blood are both used for further genomic studies.

## **10. If my patient is locally EGFR or ALK positive, do I need to wait for results on ALCHEMIST-screening before enrolling the patient onto one of the treatment trials?**

No, you do not need to wait for the results. Patients who are locally positive for EGFR or ALK can register to one of the treatment trials immediately after registering for ALCHEMIST-screening, without waiting for genotyping results from Response Genetics.

## **11. Are there shipping kits available for the block and blood collection?**

No, there are no shipping kits available for those submissions. The instructions about how to ship the materials are in the protocol.

**12. I have a patient with adenosquamous carcinoma. Is she eligible?**

Yes, she is eligible. The eligibility for ALCHEMIST-screening has been updated with Update #1 to specifically allow patients with adenosquamous carcinoma, as this is a subtype of lung adenocarcinoma.

**13. I have a patient with a second primary lung cancer. Would they be eligible?**

No, a second primary lung cancer is considered a concurrent malignancy therefore such a patient would not be eligible for ALCHEMIST.