# Clinical Trials Data EGFR - Document 59

# Molecular Profiling and Targeted Therapy for Advanced Non-Small Cell Lung Cancer, Small Cell Lung Cancer, and Thymic Malignancies

## Clinical Trial: https://clinicaltrials.gov/study/NCT01306045

"eligibilityCriteria": "\* ELIGIBILITY CRITERIA FOR INITIAL ENROLLMENT:\n\* Patients with histologically confirmed advanced Non-Small Cell Lung Cancer, (NSCLC), Small Cell Lung Cancer (SCLC) and thymic malignancies for whom surgical resection or multimodality therapy with curative intent is not feasible. For patients with Stage III NSCLC, who can be encompassed by a radiation port, definitive radiation therapy (XRT) should have been performed first when possible.\n\* Individuals who meet the eligibility criteria for epidermal growth factor receptor (EGFR) germline mutation testing but who do not have advanced cancer as defined in 3.1.1 may enroll for EGFR germline mutation testing only and will not be eligible for the treatment or NOS arms.\n\* Patients with advanced cancer must meet one of the following criteria (does not apply to first degree relatives or individuals with pre-invasive histology enrolling only for EGFR germline mutation testing):\n\n \* Patients must have biopsiable disease and be willing to undergo biopsy for molecular profiling\n\nOR\n\n-Patients must have enough and adequate archival material from a previous biopsy to perform molecular profiling analyses. The adequacy of the material provided will be determined by the principal investigator in conjunction with the laboratories performing the molecular profiling analyses\n\nOR\n\n\* Patients must have previously undergone a successful molecular profiling of their tumor with mutation analysis of the genes described in section 5.2, as part of this protocol (crossover patients) or other molecular profiling protocols such as the Lung Cancer Mutation Consortium protocol among others.\n\* Age greater than or equal to18 years.\n\nEXCLUSION CRITERIA:\n\n1. Patients who have had major surgery, chemotherapy or radiotherapy within 2 weeks prior to entering the study or those who have not recovered from adverse events due to agents administered more than 2 weeks earlier.\n2. Patients may not be receiving any other investigational agents or other medications for the treatment of their malignancy.\n3. Patients with symptomatic brain metastases should be excluded from this clinical trial because of their poor prognosis and because they often develop progressive neurologic dysfunction that would confound the evaluation of neurologic and other adverse events. However, patients who have had treatment for their brain metastases and whose brain metastatic disease status has remained stable for at least 1 week after the end of brain radiation may be enrolled to undergo molecular profiling at the discretion of the principal investigator. In addition, brain metastatic disease should be stable for at least 4 weeks, before the patients can be enrolled in any of the experimental treatment arms.\n4. Patients with any condition (e.g., gastrointestinal tract disease resulting in an inability to take oral medication or a requirement for intravenous (IV) alimentation, prior surgical procedures affecting absorption, or active peptic ulcer disease) that impairs their ability to swallow and retain tablets are excluded.\n5. Any uncontrolled medical illness that precludes the patient from undergoing a biopsy for molecular profiling and/or receiving treatment under one of the experimental arms of the study should be excluded. These conditions include but are not limited to:\n\n \* Ongoing or uncontrolled, symptomatic congestive heart failure (Class III or IV as defined by the New York Heart Association (NYHA) functional classification system (see Appendix D).\n \* Uncontrolled hypertension\n \* Unstable angina pectoris\n \* Cardiac arrhythmia\n \* Uncontrolled diabetes\n \* Uncontrolled psychiatric illness/social situations that would limit compliance with study requirements.\n6. Patients with corrected QT interval (QTc) prolongation (defined as a QTc interval equal to or greater than 500 msec) or other significant electrocardiogram (ECG) abnormalities are excluded.\n7. Caution should be used if patients are required to use a concomitant medication that can prolong the Q wave T wave (QT) interval and efforts should be made to switch to a different medication before the patient begins treatment under an experimental arm. See Appendix E for a table of medications with the potential to prolong the QTc interval. A comprehensive list of agents with the potential to cause QTc prolongation can be found at: http://www.azcert.org/medical-pros/drug-lists/bycategory.cfm\n8. The eligibility of patients taking medications that are potent inducers or inhibitors of that enzyme will be determined following a review of their case by the Principal Investigator. (A list of potent Cytochrome P450 3A4 (CYP3A4) inducers or inhibitors can be found in Appendix F). Every effort should be made to switch patients taking such agents or substances to other medications before they begin treatment with one of the experimental drug included in this protocol, particularly patients with gliomas or brain metastases who are taking enzyme-inducing anticonvulsant agents. A comprehensive list of medications and substances known or with the potential to alter the pharmacokinetics of sunitinib through CYP3A4 is provided in Appendix F.\n9. Patients with tumor amenable to potentially curative therapy as assessed by the investigator.\n10. Pregnant women are excluded from this study because many of the Food and Drug Administration (FDA) approved agents and investigational agents in this trial have the potential for teratogenic or abortifacient effects. Because there is an unknown but potential risk for adverse events in nursing infants secondary to treatment of the mother with these agents, breastfeeding should be discontinued if the mother is treated in this protocol. These potential risks may also apply to other agents used in this study.",  
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Question:  
Based on the following clinical trial information, would a patient with a EGFR gene mutation be eligible for the clinical trial?

Answer:  
Based on the eligibility criteria provided for the clinical trial, a patient with an EGFR gene mutation would be eligible for the trial, provided they meet the other conditions outlined for patients with advanced non-small cell lung cancer (NSCLC) or the other specified conditions.  
  
Here are the relevant conditions from the eligibility criteria:  
1. \*\*Histologically Confirmed Advanced NSCLC\*\*: A patient with a confirmed advanced NSCLC could be eligible.  
2. \*\*Molecular Profiling Requirement\*\*: The patient must have either:  
 - A biopsiable disease and be willing to undergo biopsy for molecular profiling, or  
 - Enough archival material from a previous biopsy for molecular profiling analyses, or  
 - Previously undergone successful molecular profiling with mutation analysis.  
  
A patient with an EGFR mutation might submit to molecular profiling as part of the trial. However, individuals who only meet the criteria for EGFR germline mutation testing without having advanced cancer would not be eligible for treatment parts of the trial—just for the germline testing aspect.  
  
In summary, the presence of an EGFR mutation does not exclude the patient from the trial. Instead, the key factors are the stage and type of the cancer and the ability and willingness to undergo the necessary molecular profiling. Other exclusion criteria and clinical conditions, such as recent surgery or other treatments, brain metastases, and medical issues that could interfere with treatment, must also be considered for actual enrollment.