# Clinical Trials Data KRAS - Document 42

# 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.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

Question:  
Based on the following clinical trial information, would a patient with a KRAS gene mutation be eligible for the clinical trial?

Answer:  
Based on the provided clinical trial eligibility criteria, it is not automatically clear whether a KRAS gene mutation would specifically make a patient ineligible or eligible for this trial without additional information on what specific genetic mutations are being investigated. The eligibility criteria emphasize having histologically confirmed advanced cancers and the need for molecular profiling, but they do not explicitly state that a KRAS mutation would exclude or specifically target those patients for the study.  
  
To determine eligibility regarding the KRAS gene mutation, we would need to know:  
1. If KRAS is one of the genes being profiled in Section 5.2 or is significant within the context of the study's objectives.  
2. Whether any specific mutations, such as KRAS, are part of the exclusion criteria in the molecular profiling analysis.  
  
Patients with molecular profiling data indicating relevant mutations for the trial are considered, so it would be important to review Section 5.2 or related specific study protocol portions to confirm the specific role of KRAS mutations. If KRAS mutations are not mentioned as an exclusion criterion and are part of the study's molecular analysis, then the patient may still be eligible assuming they meet all other criteria. Always consult with the clinical trial administrators or principal investigators for definitive guidance on specific genetic eligibility.