# Clinical Trials Data KRAS - Document 34

# Collaborative Advanced Stage Tissue Lung Cancer (CASTLE) Network

## Clinical Trial: https://clinicaltrials.gov/study/NCT01574300

"eligibilityCriteria": "Inclusion Criteria:\n\n\* M1A or B NSCLC with any number of prior therapies or any stage Small cell Lung Cancer (SCLC) with any number of prior therapies\n\* Planned systemic therapy (i.e. intent to treat)\n\* Provision of written informed consent for biospecimen storage, broad genetic and proteomic analysis of tumor and normal tissues, without restrictions, AND correlation with outcome data\n\* Aged 18 years and over.\n\* Measurable or evaluable disease.\n\* ECOG performance status of 0-2 with expected survival of at least 3 months.\n\* Tumor specimens:\n\* Tumor specimens:\n\* 4.7.1 First Priority: availability of a minimum of a 1 X 10 mm core fresh frozen tumor, or \u22653 mm diameter spherical pellet from a pleural effusion (\u226550% tumor cells), or \u22653 mm diameter spherical pellet from a fine needle aspirate (\u226550% tumor cells) from clinically indicated interventional procedures, with no systemic anti-cancer therapy or radiation to all sites of evaluable disease between collection of the biopsy and entry into the study (e.g. if a brain metastasis was radiated but the lung tumor was not, then the latter could still be biopsied and the subject enrolled after radiation therapy of the brain metastasis (and vice versa)).\n\nor\n\n\* Second Priority: availability of paraffin-embedded tumor (via biopsies or pleural effusions) at least 5 X 5 mm (3 X 3 mm for pleural effusions) cross-sectional tumor area, with no systemic anti-cancer therapy or radiation to all sites of evaluable disease between collection of the biopsy and entry into the study; the collection of the paraffin-embedded tissues may have taken place up to 12 months prior to enrollment in CASTLE.\n\* Willingness to undergo all study collection procedures and sample analyses including prerequisite baseline molecular testing via ResponseDX: Lung (Response Genetics Inc.) and VeriStrat (Biodesix) - see 6.3 below for details.\n\* Exclusion criteria\n\* Other co-existing malignancies except for basal cell carcinoma or cervical cancer in situ.\n\* Compromise of patient diagnosis or staging if tissue is harvested for research",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
],  
 "studyPopulation": "Advanced stage lung cancer patients",

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 information provided from the clinical trial's inclusion and exclusion criteria, there is no specific mention of the KRAS gene mutation status as a basis for exclusion or inclusion. The eligibility criteria focus on the type and stage of lung cancer, the intent to treat with systemic therapy, the availability and condition of tumor specimens, and general performance status and survival expectations.  
  
As a KRAS gene mutation is not specifically addressed in the eligibility criteria, a patient with a KRAS mutation would not automatically be excluded based on that mutation alone. However, it is important that the patient meets all other specified inclusion criteria and does not have any of the conditions listed in the exclusion criteria. It's always good practice for the patient or their healthcare provider to confirm eligibility with the trial organizers directly, as there may be additional considerations or updates to the trial criteria.