# Clinical Trials Data ALK - Document 3

# 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 ALK gene mutation be eligible for the clinical trial?

Answer:  
Based on the eligibility criteria provided, a patient with an ALK gene mutation could potentially be eligible for the clinical trial, as the criteria do not specifically exclude patients with ALK mutations. The trial seems to be open to patients with advanced-stage non-small cell lung cancer (NSCLC) or small cell lung cancer (SCLC), regardless of specific gene mutations, as long as they meet the other inclusion criteria.  
  
Here are the key inclusion and exclusion points that would apply:  
  
1. \*\*Patient Diagnosis\*\*: The trial includes patients with M1A or B NSCLC or any stage SCLC with any number of prior therapies. An ALK mutation is a subtype of NSCLC, which suggests eligibility.  
  
2. \*\*Planned Systemic Therapy\*\*: Patients must have planned systemic therapy, indicating treatment intent.  
  
3. \*\*Biopsies and Tissue Requirement\*\*: Patients must have appropriate tumor specimens available, either fresh frozen or paraffin-embedded, and no systemic anti-cancer therapy or radiation should occur between collection and study entry.  
  
4. \*\*Consent for Sample Analysis\*\*: The patient must provide consent for biospecimen storage, genetic and proteomic analysis, and be willing to undergo baseline molecular testing.  
  
5. \*\*Performance Status\*\*: Patients need an ECOG performance status of 0-2 with an expected survival of at least 3 months.  
  
6. \*\*Exclusion Criteria\*\*: There are no specific exclusions for genetic mutations like ALK in the given criteria. Other malignancies are excluded, except basal cell carcinoma or cervical cancer in situ.  
  
Since the criteria provided do not specifically address exclusion of patients with specific genetic mutations such as ALK, an ALK-positive patient matching the other necessary criteria could be eligible for this trial. However, it is always recommended to confirm with the specific clinical trial coordinators or investigators for any additional mutation-specific eligibility details.