# 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:  
This trial information \*\*does not\*\* specify that an ALK gene mutation is required for inclusion, nor does it exclude patients with ALK mutations. The criteria focus on the stage and type of lung cancer (M1A or B NSCLC, or any stage SCLC), prior therapies (any number allowed), and the ability to provide suitable tumor samples. Therefore, a patient with an ALK mutation \*could\* be eligible provided they meet all other inclusion criteria and none of the exclusion criteria.