# Clinical Trials Data ALK - Document 4

# CPCT-05 Biopsy Protocol Patient Selection

## Clinical Trial: https://clinicaltrials.gov/study/NCT01904916

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Locally advanced (incurable) or metastatic cancer from a histological or cytological proven solid tumor\n\* Indication for systemic treatment with anti-cancer agents (with no treatment options with curative intent)\n\* Measurable locally advanced (incurable) or metastatic lesion(s), according to RECIST 1.1 criteria.\n\* Safe biopsy of a metastatic or locally advanced lesion possible\n\* No contraindications for lidocaine (or its derivatives) and/or midazolam and/or phentanyl\n\* Adequate organ function\n\* WHO performance status 0-2\n\* Age \\> 18 yr\n\* Expected adequacy to follow up\n\* Written informed consent\n\nExclusion Criteria:\n\n\u2022 If one or more of the above mentioned inclusion criteria is not met",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

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 provided eligibility criteria for the clinical trial, there is no specific mention of genetic mutations like ALK (anaplastic lymphoma kinase) being a factor for exclusion or inclusion. The trial appears to be focused on patients with locally advanced or metastatic solid tumors who require systemic treatment without other curative options.  
  
However, as the criteria do not explicitly address the presence of an ALK gene mutation, it seems that having an ALK mutation would not automatically disqualify the patient, provided they meet all other inclusion criteria and none of the exclusion criteria.   
  
If the ALK gene mutation does not affect the treatment regimen proposed in the trial or pose any contraindications, and if the patient meets all other eligibility requirements such as having measurable lesions, no lidocaine/midazolam/phenytoin contraindications, adequate organ function, and so forth, they could potentially be eligible to participate in the trial.  
  
For a definitive answer, it would be best for the patient or their healthcare provider to consult directly with the trial investigators. They can verify if there are any additional considerations related to the ALK gene mutation not covered in the general eligibility criteria.