# 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:  
The provided information doesn't mention specific gene mutations as inclusion or exclusion criteria. The criteria focus on having advanced/metastatic solid tumors, needing systemic anti-cancer treatment, and being able to undergo a biopsy. Therefore, having an ALK gene mutation \*doesn't automatically exclude\* a patient, but it also \*doesn't guarantee\* eligibility. Whether the patient qualifies depends on if they meet \*all\* the other inclusion criteria and \*none\* of the exclusion criteria. The presence of the ALK mutation might be relevant to the "indication for systemic treatment" criterion if targeted therapy for ALK-positive tumors is available or not.