# Clinical Trials Data ALK - Document 30

# A Phase 1b Study Of Axitinib In Combination With Crizotinib In Patients With Advanced Solid Tumors

## Clinical Trial: https://clinicaltrials.gov/study/NCT01999972

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Diagnosis - Dose Escalation Phase: Histologically or cytologically confirmed diagnosis of advanced solid tumor that is resistant to standard therapy or for which no standard therapy is available.\n\* Diagnosis - Dose Expansion Phase: Histologically or cytologically confirmed advanced RCC with a component of clear cell subtype\n\* Dose Expansion Phase: at least one measureable lesion as defined by RECIST \\[Response Evaluation Criterion in Solid Tumors\\] version 1.1.\n\* ECOG \\[Eastern Cooperative Oncology Group\\] Performance Status 0 or 1.\n\nExclusion Criteria:\n\n\* Major surgery \\<4 weeks or radiation therapy \\<2 weeks of patient registration.\n\* History of or known active seizure disorder, brain metastases, spinal cord compression, or carcinomatous meningitis, or new evidence of brain or leptomeningeal disease.\n\* Dose Expansion Phase only: diagnosis of any other malignancy within 2 years prior to registration.",  
 "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 eligibility criteria don't mention anything specifically about ALK gene mutations. Therefore, having an ALK mutation doesn't automatically exclude or include a patient.  
  
Here's a breakdown:  
  
\* \*\*Dose Escalation Phase:\*\* A patient with an ALK mutation \*could\* be eligible if they have an advanced solid tumor resistant to standard therapy or for which no standard therapy exists. The ALK mutation itself isn't a factor in this phase.  
\* \*\*Dose Expansion Phase:\*\* This phase is specifically for advanced Renal Cell Carcinoma (RCC) with a clear cell component. A patient with an ALK mutation would only be eligible if they \*also\* met this RCC criteria, along with the other requirements (measurable lesion, ECOG status, and exclusion criteria).  
  
In short, the ALK mutation is not a deciding factor. The patient's cancer type and stage are the primary determinants of eligibility.