# 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:  
Based on the provided clinical trial information, the eligibility of a patient with an ALK gene mutation would depend on several factors beyond just the genetic mutation itself. The key eligibility criteria to consider are:  
  
1. \*\*Diagnosis Requirement:\*\*  
 - For the Dose Escalation Phase, the patient must have a histologically or cytologically confirmed diagnosis of an advanced solid tumor that is resistant to standard therapy or for which no standard therapy is available.  
 - For the Dose Expansion Phase, the patient must have a confirmed diagnosis of advanced renal cell carcinoma (RCC) with a clear cell subtype.  
  
2. \*\*Performance Status:\*\*  
 - The patient must have an ECOG Performance Status of 0 or 1.  
  
3. \*\*Exclusion Criteria:\*\*  
 - No major surgery within 4 weeks or radiation therapy within 2 weeks of registration.  
 - No history of or active seizure disorder, brain metastases, spinal cord compression, or carcinomatous meningitis, or new evidence of brain or leptomeningeal disease.  
 - No other malignancy diagnosed within 2 years prior to registration (for the Dose Expansion Phase).  
  
The presence of an ALK gene mutation is not mentioned as a specific inclusion or exclusion criterion. Therefore, whether a patient with an ALK mutation is eligible largely depends on the type and status of their cancer (advanced solid tumor or RCC with clear cell subtype) and their overall clinical condition matching the criteria outlined. If the tumor type with an ALK mutation fits within the conditions of the trial phases, the mutation itself does not automatically disqualify the patient. It is best to review these requirements with the trial coordinators or the patient's healthcare provider for a definitive assessment.