# Clinical Trials Data ALK - Document 2

# AUY922 for Advanced ALK-positive NSCLC

## Clinical Trial: https://clinicaltrials.gov/study/NCT01752400

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Histologically or cytologically confirmed advanced NSCLC\n\* Tumor characterized by abnormalities in ALK\n\* Required to provide archival tissue in the form of 5 formalin fixed paraffin embedded sections\n\* Have acquired resistance to treatment with an ALK-TKI\n\* At least one measurable lesion as defined by RECIST criteria\n\* Life expectancy of at least 12 weeks\n\nExclusion Criteria:\n\n\* Pregnant or breastfeeding\n\* Discontinued ALK TKI more than four weeks prior to enrollment\n\* Unresolved diarrhea greater than or equal to CTCAE grade 1\n\* Not willing to use double barrier methods of contraception\n\* Prior anti-neoplastic treatment with any HSP90 or HDAC inhibitor compound\n\* Have received cytoxic chemotherapy in the intervening period since discontinuation of an ALK-TKI\n\* Have undergone major surgery within 2 weeks prior to starting study drug\n\* Any concurrent or uncontrolled illness\n\* Any known disorders due to a deficiency in bilirubin glucuronidation\n\* Taking therapeutic doses of warfarin\n\* Any serious cardiac disorders or abnormalities\n\* Concurrent malignancies or invasive cancers diagnosed within the past 2 years except for adequately treated basal cell cancer of the skin or in situ cancers\n\* Known to be HIV positive\n\* Known hypersensitivity to any of the study drugs or their excipients\n\* Participation in another clinical study within 30 days before the first study treatment",  
 "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:  
A patient with an ALK gene mutation \*might\* be eligible, but more information is needed. The inclusion criteria specify "Tumor characterized by abnormalities in ALK" and "Have acquired resistance to treatment with an ALK-TKI". Simply having the ALK mutation isn't enough. The patient must also have already been treated with an ALK tyrosine kinase inhibitor (ALK-TKI) and developed resistance to it. If the patient hasn't been treated with an ALK-TKI, they would not be eligible for this particular trial.