# Clinical Trials Data ALK - Document 29

# Sunitinib in Never-Smokers With Lung Adenocarcinoma

## Clinical Trial: https://clinicaltrials.gov/study/NCT01829217

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Histologically or cytologically confirmed advanced (stage IV or recurrent) non-small cell lung cancer\n\* Adenocarcinoma histology of any variant, including adenosquamous histology\n\* Wild-type for mutations in EGFR, KRAS and ALK\n\* Must have \\< 100 cigarettes smoked lifetime OR known to harbor a RET rearrangement OR another potentially targetable genomic alteration as defined per protocol\n\* Disease must be measureable per RECIST 1.1\n\* At least one prior systemic therapy (adjuvant or palliative)\n\* 18 years or older\n\* Life expectancy of greater than 4 weeks\n\* Adequate ECOG performance status 0 or 1\n\* Adequate organ function as defined in the protocol\n\* Adequate tumor tissue for the correlative analyses on study, or must undergo a biopsy to obtain adequate tissue\n\nExclusion Criteria:\n\n\* Pregnant or breastfeeding\n\* Chemotherapy within 4 weeks of entering study, or lack of recover from adverse events to grade 1 or less due to systemic agents administered more than 4 weeks earlier\n\* Radiation therapy within 2 weeks prior to entering study\n\* Major surgery within 4 weeks prior to entering the study\n\* Receiving any other investigational agents\n\* Known untreated, symptomatic or progressive brain metastases; presence of carcinomatous meningitis; history of intracranial hemorrhage or brain metastases requiring chronic steroids\n\* History of allergic reactions attributed to compounds of similar chemical or biologic composition to sunitinib\n\* Use of certain inhibitors and inducers of CYP3A4\n\* Grade 3 or 4 hemoptysis or hemorrhage within 4 weeks prior to study entry\n\* History of significant bleeding disorder unrelated to cancer\n\* Poorly controlled hypertension\n\* Severe cardiovascular disease\n\* Prolongation of corrected QT interval\n\* History of a different malignancy except: cervical cancer in situ, basal or squamous cell carcinoma of the skin, low risk centralized prostate cancer\n\* HIV positive on combination antiretroviral therapy",  
 "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:  
No. The inclusion criteria explicitly state "Wild-type for mutations in EGFR, KRAS and ALK". This means the patient must \*not\* have mutations in these genes to be eligible. Since the patient has an ALK mutation, they are excluded.