# Clinical Trials Data KRAS - Document 12

# Assess Efficacy & Safety of Selumetinib in Combination With Docetaxel in Patients Receiving 2nd Line Treatment for v-Ki-ras2 Kirsten Rat Sarcoma Viral Oncogene Homolog (KRAS) Positive NSCLC

## Clinical Trial: https://clinicaltrials.gov/study/NCT01933932

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Provision of signed, written and dated informed consent prior to any study specific procedures\n\* Male or female, aged 18 years or older\n\* Histological or cytological confirmation of locally advanced or metastatic NSCLC (IIIB-IV)\n\* KRAS mutation positive tumour sample as determined by the designated testing laboratory\n\* Failure of 1st line anti-cancer therapy due to radiological documentation of disease progression in advanced disease or subsequent relapse of disease following 1st line therapy\n\nExclusion Criteria:\n\n\* Mixed small cell and non-small cell lung cancer histology.\n\* Received \\>1 prior anti-cancer drug regimen for advanced or metastatic NSCLC. Patients who develop disease progression while on switch maintenance therapy (maintenance using an agent not in the first-line regimen) will not be eligible.\n\* Receiving or have received systemic anti-cancer therapy within 30 days prior to starting study treatment\n\* Other concomitant anti-cancer therapy agents excepts steroids\n\* Prior treatment with a Mitogen-Activated protein Kinase (MEK) inhibitor or any docetaxel-containing regimen (prior treatment with paclitaxel is acceptable).\n\* Last radiation therapy within 4 weeks prior starting study treatment, or limited field of radiation for palliation within 7 days of the first dose of 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 KRAS gene mutation be eligible for the clinical trial?

Answer:  
Yes, a patient with a KRAS mutation would be \*potentially\* eligible for this trial. The inclusion criteria specifically state "KRAS mutation positive tumour sample".  
  
However, eligibility depends on meeting \*all\* inclusion criteria and \*none\* of the exclusion criteria. Just having the KRAS mutation isn't enough. The patient would also need to meet conditions such as:  
  
\* Age 18 or older  
\* Locally advanced or metastatic NSCLC (IIIB-IV)  
\* Failure of 1st-line therapy  
\* Not having received >1 prior anti-cancer drug regimen for advanced or metastatic NSCLC  
\* And several other criteria.  
  
Therefore, while the KRAS mutation is required, it's not the sole determinant of eligibility. A full review of the patient's medical history and current condition is necessary to determine final eligibility.