# Clinical Trials Data KRAS - Document 1

# A Phase I Study of Nilontinib and Cetuximab in Patients With Solid Tumors

## Clinical Trial: https://clinicaltrials.gov/study/NCT01871311

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Recurrent and/or metastatic Kras wildtype colorectal cancer or squamous cell carcinoma of the head and neck\n2. Previous therapy:\n\n 1. Patients must have progressed after standard therapy for metastatic/recurrent disease, including irinotecan and oxaliplatin-containing regimens for patients with CRC and platinum-containing regimens for patients with H\\&NSCC.\n 2. Patients may have received cetuximab or panitumumab previously\n3. Ability to swallow medication tablets by mouth (which may include taking nilotinib mixed in apple sauce)\n4. At least one measurable lesion by RECIST criteria\n5. A tumor lesion that can be readily biopsied using a core needle via clinical exam or image-guidance.\n6. Over the age of 18 years and able to provide informed consent\n7. Adequate kidney, liver, and bone marrow function as follows:\n\n 1. Hemoglobin \\>/= 8.0 gm/dL\n 2. Absolute neutrophil count \\>/= 1500\n 3. Platelet count \\>/= 100,000\n 4. Creatinine within institutional normal limits or glomerular filtration rate \\> 60\n 5. Total bilirubin f. AST and ALT\n8. Life expectancy of greater than 3 months\n9. ECOG performance status\n10. Normal left ventricular ejection fraction, defined as EF \\> 50%\n\nExclusion Criteria:\n\n1. Chemotherapy or surgery within 4 weeks prior to treatment start\n2. Radiation treatment within 3 weeks prior to treatment start\n3. Prior therapy with nilotinib, ponatinib, dasatinib, or imatinib\n4. Untreated brain metastases or neurologically unstable central nervous system metastases; CNS metastases will be considered stable if there is no new nor enlarging lesions for one month, and the patient remains off steroids and anti-epileptics for the same time period\n5. Any severe or uncontrolled medical condition or other condition that could affect participation in this study, including: unstable angina, uncontrolled hypertension, serious uncontrolled cardiac arrhythmia, uncontrolled infection, or myocardial infarction\n6. Diarrhea \\> Grade 1 at baseline\n7. Concomitant medication or herbal therapy known to inhibit CYP3A4\n8. Gastrointestinal tract disease resulting in the inability to take oral medication or a requirement for IV alimentation, prior surgical procedures affecting absorption, or active peptic ulcer disease\n9. Ongoing ventricular cardiac dysrhythmias of NCI CTCAE grade \\>/= 2\n10. Subjects with a history of serious ventricular arrhythmia (ventricular tachycardia or ventricular fibrillation \\>/= 3 beats in a row)\n11. Serious cardiac arrhythmia requiring medication\n12. QTc interval \\> 500 msec\n13. Female patients who are pregnant or breast feeding, or adults who are of reproductive potential and are unwilling to refrain from conceiving a child during study treatment\n14. Patients unwilling or unable to comply with the protocol, or provide informed consent",  
 "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:  
No. The inclusion criteria specifically state "Recurrent and/or metastatic \*\*Kras wildtype\*\* colorectal cancer or squamous cell carcinoma of the head and neck". A patient with a KRAS mutation (not wildtype) would be excluded.