# Clinical Trials Data KRAS - Document 9

# Panitumumab in Cetuximab Refractory KRAS Wild-Type Colorectal Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT00842257

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Histologically or cytologically confirmed diagnosis of colorectal adenocarcinoma and measurable disease by RECIST criteria on CT or MRI\n\* Treated with cetuximab as part of their last treatment regimen for at least 4 weeks and must have been taken off cetuximab therapy for disease progression. Patients may or may not have been treated with 5-FU (5-Fluorouracil), oxaliplatin, irinotecan and bevacizumab. There is no maximal number of pre-existing treatment regimens. At least 2 weeks must have elapsed between previous anticancer therapy and the start of treatment on protocol, AND resolution of any skin rash related to prior treatment with epidermal growth factor receptor inhibitor\n\* ECOG (Eastern Cooperative Oncology Group) Performance Status 0, 1 or 2\n\* Life expectancy of greater than 3 months\n\* Normal organ, metabolic, and marrow function as defined in the protocol\n\* A wild-type tumor K-RAS gene (Kirsten rat sarcoma viral oncogene homolog) as determined by sanger sequencing of exon 2 from tumor DNA\n\* 18 years of age or older\n\nExclusion Criteria:\n\n\* History of untreated and or progression central nervous system metastases\n\* History of another primary cancer except: curatively treated in situ cervical cancer or breast; curatively resected non-melanoma skin cancer; other primary solid tumor curatively treated with no known active disease present and no treatment administered for 3 years or more prior to enrollment\n\* Intolerance to cetuximab leading to drug discontinuation due to rash, GI toxicity, or other grade 3 or 4 toxicities\n\* Radiotherapy \\< 14 days prior to enrollment\n\* Systemic chemotherapy, hormonal therapy, immunotherapy, or experimental or approved proteins/antibodies \\< 14 days before enrollment\n\* Subjects requiring chronic use of immunosuppressive agents\n\* Any investigational agent or therapy 30 days prior to enrollment\n\* Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with any study requirements\n\* History of interstitial lung disease\n\* Women who test positive for serum or urine pregnancy test or who are breast feeding",  
 "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 explicitly state that the patient must have a \*\*wild-type\*\* K-RAS gene. A patient with a KRAS mutation would be excluded from this trial.