# Clinical Trials Data KRAS - Document 36

# Simvastatin and Panitumumab in Treating Patients With Advanced or Metastatic Colorectal Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01110785

"eligibilityCriteria": "DISEASE CHARACTERISTICS:\n\n\* Diagnosis of colorectal cancer\n\n \* Advanced or metastatic disease\n\* Failed prior fluorouracil-, oxaliplatin- and irinotecan-containing regimens\n\n \* In case of progressive disease within 6 months after start of adjuvant fluorouracil-, oxaliplatin-, and irinotecan-containing regimens, the adjuvant therapy is considered to be treatment for metastatic disease\n\* Mutant-type k-ras status (mutation in codon 12, 13, or 61) on tumor material\n\* Measurable disease according to RECIST criteria version 1.1\n\* Progressive disease in the past 3 months according to RECIST criteria version 1.1\n\* No symptomatic brain metastases, defined as any symptoms during the past 6 months\n\nPATIENT CHARACTERISTICS:\n\n\* WHO performance status 0-2\n\* WBC \u2265 2.0 x 10\\^9/L\n\* ANC \u2265 1.5 x 10\\^9/L\n\* Platelet count \u2265 100 x 10\\^9/L\n\* Hemoglobin \u2265 9 g/dL\n\* Serum bilirubin \u2264 1.5 times upper limit of normal (ULN)\n\* AST/ALT \u2264 3 times ULN (\u2264 5 times ULN in case of liver metastases)\n\* Creatinine clearance \u2265 60 mL/min\n\* Magnesium normal\n\* Calcium normal\n\* Creatine phosphokinase \u2264 2.5 times ULN\n\* Not pregnant or nursing\n\* Not planning to become pregnant within 6 months after the end of study treatment\n\* Fertile patients must use highly effective contraception during and for 6 months after completion of study therapy\n\* No noncompliance in previous studies\n\* No alcohol use \\> 4 units/day or unwilling to abstain from use\n\* No history of interstitial lung disease (e.g., pneumonitis or pulmonary fibrosis) or signs of interstitial lung disease on baseline CT scan\n\* No clinically significant cardiovascular disease (including myocardial infarction, unstable angina, symptomatic congestive heart failure, or serious uncontrolled cardiac arrhythmia) \\< 1 year prior to study\n\* No symptomatic hypothyroidism\n\* No history of toxicity during statin use\n\nPRIOR CONCURRENT THERAPY:\n\n\* See Disease Characteristics\n\* No prior EGFr-therapy, including monoclonal antibodies (e.g., panitumumab or cetuximab)\n\* No concurrent verapamil, amiodarone, or dronedarone or unwilling to abstain from use",  
 "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 gene mutation \*could\* be eligible for this trial. The eligibility criteria specifically states: "Mutant-type k-ras status (mutation in codon 12, 13, or 61) on tumor material".  
  
However, having the KRAS mutation is only \*one\* of the requirements. The patient must \*also\* meet all the other eligibility criteria related to disease characteristics, patient characteristics, and prior/concurrent therapy. If they fail to meet even one of these other criteria, they would not be eligible.