# Clinical Trials Data BRAF - Document 8

# FOLFOXIRI Plus Panitumumab In Kras and Braf Wild-Type Metastatic Colorectal Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01358812

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Histologically confirmed colorectal adenocarcinoma;\n\* Availability of formalin-fixed paraffin embedded tumor block from primary or metastasis;\n\* KRAS and BRAF wild-type status of primary colorectal cancer or related metastasis;\n\* Unresectable and measurable metastatic disease according to RECIST criteria;\n\* Male or female, aged \\>/= 18 years and \\</= 75 years;\n\* ECOG PS \\< 2 if aged \\< 71 years;\n\* ECOG PS = 0 if aged 71-75 years;\n\* Life expectancy of more than 3 months;\n\* Adequate haematological function: ANC \u2265 1.5 x 109/L; platelets \u2265 100 x 109/L, Hb \u2265 9 g/dL;\n\* Adequate liver function: serum bilirubin \u2264 1.5 x ULN; alkaline phosphatase and transaminases \u2264 2.5 x ULN (in case of liver metastases \\< 5 x ULN);\n\* Serum creatinine \u2264 1.5 x ULN;\n\* Previous adjuvant chemotherapy is allowed if more than 12 months have elapsed between the end of adjuvant therapy and first relapse;\n\* At least 6 weeks from prior radiotherapy and 4 weeks from surgery;\n\* Written informed consent to experimental treatment and pharmacogenomic analyses;\n\* Magnesium \u2265 lower limit of normal;\n\* Calcium \u2265 lower limit of normal.\n\nExclusion Criteria:\n\n\* Prior palliative chemotherapy;\n\* Prior treatment with EGFR inhibitors;\n\* Symptomatic peripheral neuropathy \u2265 2 grade NCIC-CTG criteria;\n\* Presence or history of CNS metastasis;\n\* Active uncontrolled infections; active disseminated intravascular coagulation;\n\* Past or current history of malignancies other than colorectal carcinoma, except for curatively treated basal and squamous cell carcinoma of the skin cancer or in situ carcinoma of the cervix;\n\* Clinically significant cardiovascular disease, for example cerebrovascular accidents (CVA) (\u2264 6 months before treatment start), myocardial infarction (\u2264 6 months before treatment start), unstable angina, NYHA \u2265 grade 2 chronic heart failure (CHF), uncontrolled arrhythmia;\n\* Fertile women (\\< 2 years after last menstruation) and men of childbearing potential not willing to use effective means of contraception;\n\* Subject pregnant or breast feeding, or planning to become pregnant within 6 months after the end of treatment;\n\* History of interstitial lung disease e.g. pneumonitis or pulmonary fibrosis or evidence of interstitial lung disease on baseline chest CT scan.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

Question:  
Based on the following clinical trial information, would a patient with a BRAF gene mutation be eligible for the clinical trial?

Answer:  
Based on the eligibility criteria provided for the clinical trial, a patient with a BRAF gene mutation would not be eligible to participate. The inclusion criteria specifically require "KRAS and BRAF wild-type status of primary colorectal cancer or related metastasis." This means the patient's colorectal cancer must not have mutations in either the KRAS or BRAF genes to be eligible for the trial. Therefore, a patient with a BRAF gene mutation would not meet these criteria and would be considered ineligible.