# 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:  
No. The inclusion criteria specifically state "KRAS and BRAF \*\*wild-type\*\* status". This means the patient \*cannot\* have a BRAF mutation to be eligible for the trial. A wild-type status means the gene is in its normal, non-mutated form.