# Clinical Trials Data BRAF - Document 9

# Study of FOLFIRI + Panitumumab Using Ultra-selection Technology of Patients With Stage IV Colorectal Cancer Refractory to Irinotecan Without Any Mutation on KRAS, PIK3Ca, BRAF and NRAS Genes Detected With Highly Sensitive Techniques

## Clinical Trial: https://clinicaltrials.gov/study/NCT01704703

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Competent to understand, sign and date an IEC-approved informed consent form.\n2. Men or women 18 years of age or older at the time the written informed consent is obtained.\n3. Histologically confirmed metastatic adenocarcinoma of the colon or rectum Wild-Type RAS (No mutation) with at least 1 measurable metastatic lesion following RECIST criteria v 1.1 and initially irresectable (non suitable for radical surgery at the inclusion time).\n4. Obtention of DNA from tumor tissue blocks sent to central lab (ICO) that is amenable for highly sensitive techniques\n5. Previous irinotecan based chemotherapy +/- bevacizumab for metastatic CCR during at least 6 weeks.\n6. Irinotecan based chemotherapy does not need to be the most recent chemotherapy administrated. There are no restrictions on numbers of treatments lines before study inclusion.\n7. Disease progression during irinotecan treatment or within 6 months after irinotecan treatment.\n8. Karnofsky status \u2265 70% .\n9. Adequate bone marrow, hepatic, renal and metabolic functions,\n\n 1. Adequate bone marrow function: neutrophils \u2265 1.5x109/ L; platelets \u2265 100x109/L; hemoglobin \u2265 9g/dL.\n 2. Hepatic functions as follows: total bilirubin count \u2264 1.5 x ULN; ALAT and ASAT \u2264 2.5 x ULN (\u2264 5 x ULN in case of liver metastasis).\n 3. Renal function: creatinine clearance \\> 50 ml/min (according Cockcroft y Gault formulae)\n 4. Metabolic functions: magnesium \u2265 lower limit of normal (LIN)\n10. Life expectancy \u2265 3 months.\n\nExclusion Criteria:\n\n1. Prior malignant tumor in the last 5 years, except a history of basal cell carcinoma of the skin or pre-invasive cervical cancer.\n2. Unresolved toxicities from prior systemic therapy and/or radiotherapy that, in the opinion of the investigator, does not qualify the patient for inclusion.\n3. Documented or suspected central nervous system metastases.\n4. Any previous antitumoral treatment (chemotherapy, hormonal therapy, radiation treatment, surgery, immunotherapy, biologic therapy) \u2264 28 days before study inclusion.\n5. Significant cardiovascular disease including unstable angina or myocardial infarction within 12 months before initiating study treatment or a history of ventricular arrhythmia.\n6. Prior anti-EGFr antibody therapy (eg, Cetuximab) or treatment small molecule EGFr tyrosine kinase inhibitors (eg, Erlotinib). Subjects who discontinue their first dose of anti-EGFR therapy (Cetuximab) because of an infusion reaction may participate in this clinical trial.\n7. Paraffin-embedded tissue or unstained tumor slides from primary or metastatic tumor not available or quality ADN not available for biomarker determination by highly sensitive techniques.\n8. History of interstitial pneumonitis or pulmonary fibrosis or evidence of interstitial pneumonitis or pulmonary fibrosis.\n9. Treatment for systemic infection within 14 days before study inclusion.\n10. Acute or sub-acute intestinal occlusion and /or active inflammatory bowel disease or other bowel disease causing chronic diarrhoea (defined as \\> 4 loose stools per day).\n11. History of Gilbert's syndrome or dihydropyrimidine deficiency.\n12. History of any medical condition that may increase the risks associated with study participation or may interfere with the interpretation of the study results.\n13. Known positive test for human immunodeficiency virus infection, hepatitis C virus, and chronic active hepatitis B infection.\n14. Subject allergic to the ingredients of the study medication or to Staphylococcus protein A.\n15. Any co-morbid disease that would increase risk of toxicity.\n16. Any kind of disorder that compromises the ability of the subject to give written informed consent and/or comply with the study procedures.\n17. Subject who is pregnant or breast feeding.\n18. Surgery (excluding diagnostic biopsy or central venous catheter placement) \u2264 28 days prior study inclusion.\n19. Woman or man of childbearing potential not consenting to use adequate contraceptive precautions.\n20. Subject unwilling or unable to comply with study requirements.\n21. Psychological, familial, sociological, or geographical condition potentially hampering compliance with the study protocol and follow-up schedule.",  
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"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. Inclusion criteria #3 specifies "Wild-Type RAS (No mutation)" for the patient's metastatic adenocarcinoma. A patient with a BRAF mutation does \*not\* qualify as wild-type RAS. They would be excluded from this trial.