# Clinical Trials Data EGFR - Document 116

# A Pilot Study of Genomic Sequencing Guided Individualized Therapy in Gastrointestinal Cancers, GITIC Study

## Clinical Trial: https://clinicaltrials.gov/study/NCT02013089

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Pathologic diagnosis of Gastrointestinal cancer\n2. The subject has a diagnosis metastatic gastrointestinal cancer, and failed from standard treatment, and no other regimen is available.\n3. The subject has measurable lesion of gastrointestinal cancer.\n4. The subject's The Eastern Cooperative Oncology Group (ECOG) performance status of 0-2.\n5. The subject has adequate hematologic function as defined by an absolute neutrophil count (ANC) \\>/= 1,500/mm3, platelet count \\>/= 100,000/mm3, White Blood Count (WBC) \\>/= 3,000/ mm3, and hemoglobin \\>/= 9 g/dL.\n6. The subject has adequate hepatic function as defined by a total bilirubin level \\</= 1.5 \\\* the upper limit of normal (ULN) (bilirubin \\>/= 1.5 \\\* ULN with known Gilbert's disease is allowed), and alkaline phosphatase, aspartate aminotransferase/alanine aminotransferase (AST/ALT) \\</= 2.5 \\\* the upper limit of normal or \\</= 5.0 \\\* ULN if liver metastases are present.\n7. Serum creatinine clearance \\>50ml/min, either by Cockcroft-Gault formula or 24-hour urine collection analysis\n8. The subject is \\>/=18 years of age.\n9. The subject has signed informed consent.\n10. Women of childbearing potential must agree to use adequate contraception (hormonal or barrier method of birth control; abstinence) prior to study entry and for the duration of study participation. Childbearing potential will be defined as women who have had menses within the past 12 months, who have not had tubal ligation, hysterectomy or bilateral oophorectomy. Should a woman become pregnant or suspect that she is pregnant while participating in this study, she should inform her treating physician immediately.\n\nExclusion Criteria:\n\n1. pregnant or breast-feeding.\n2. Subjects will be excluded for other concurrent severe and/or uncontrolled medical disease which could compromise participation in the study\n3. without enough tumor sample for analysis.\n4. Refuse to sign the informed consent.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

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

Answer:  
Based on the provided eligibility criteria for the clinical trial, there is no mention of EGFR gene mutation as either an inclusion or exclusion criterion. Therefore, the presence of an EGFR gene mutation does not automatically affect eligibility for this trial.  
  
The key criteria that determine eligibility are related to the diagnosis and treatment status, measurable lesions, performance status, hematologic and hepatic function, renal function, age, informed consent, and contraceptive measures for women of childbearing potential. As long as the patient meets all the inclusion criteria and none of the exclusion criteria, they should be eligible to participate in the trial, regardless of their EGFR gene mutation status.