# Clinical Trials Data KIT - Document 2

# 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 KIT gene mutation be eligible for the clinical trial?

Answer:  
Based on the provided eligibility criteria for the clinical trial, a patient with a KIT gene mutation would not be explicitly excluded unless the mutation falls under a specific category of "other concurrent severe and/or uncontrolled medical disease which could compromise participation in the study."   
  
However, the eligibility criteria do not mention any specific genetic mutations, including the KIT gene mutation, as a factor for exclusion. Therefore, if the patient meets all the other inclusion criteria and none of the exclusion criteria apply (such as concurrent severe medical conditions), they would likely be eligible to participate in the clinical trial.  
  
It is important for the patient or their healthcare provider to discuss specific details related to the KIT gene mutation and how it might interact with the study design or treatment, with the clinical trial coordinators for further clarification.