# 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:  
The provided information doesn't state that a KIT gene mutation is \*required\* for the trial. It \*also\* doesn't exclude patients with a KIT mutation. Therefore, having a KIT mutation doesn't automatically disqualify a patient.  
  
A patient with a KIT gene mutation \*could\* be eligible for this trial \*\*IF\*\* they also meet \*all\* of the other inclusion criteria and \*none\* of the exclusion criteria. Specifically, they would need to:  
  
\* Have a pathologically diagnosed metastatic gastrointestinal cancer.  
\* Have failed standard treatment with no other regimen available.  
\* Have measurable gastrointestinal cancer lesions.  
\* Have an ECOG performance status of 0-2.  
\* Meet the specified hematologic and hepatic function requirements.  
\* Have a creatinine clearance >50ml/min.  
\* Be 18 years or older.  
\* Sign informed consent.  
\* (If a woman of childbearing potential) Agree to use adequate contraception.  
  
And they \*cannot\*:  
  
\* Be pregnant or breastfeeding.  
\* Have other severe/uncontrolled medical conditions that would compromise participation.  
\* Have insufficient tumor sample for analysis.  
\* Refuse to sign informed consent.  
  
So, the presence of a KIT mutation itself is not a determining factor for eligibility.