# Clinical Trials Data KIT - Document 7

# A Study of Famitinib in Patients With Advanced Colorectal Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01762293

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Histologically or cytologic confirmed recurrent and/or metastatic CRC and previously received at least two lines of standard therapy failure(must include 5-Fu,irinotecan and oxaliplatin)\n\* At least one measurable lesion, larger than 10 mm in diameter by spiral CT scan(scanning layer \u2264 5 mm )\n\* age \u2265 18 and \u2264 70\n\* ECOG 0-1\n\* Life expectancy of more than 3 months\n\* More than 4 weeks after operation, chemotherapy, radiotherapy, cytotoxic agents or tyrosine kinase inhibitors\n\* Signed and dated informed consent\n\* Willingness and ability to comply with scheduled visits, treatment plans, laboratory tests, and other study procedure.\n\nExclusion Criteria:\n\n\* Before or at the same time any, second malignancies except cured basal cell carcinoma of skin and carcinoma in-situ of uterine cervix\n\* Prior therapy with tyrosine kinase -inhibitor agent targeting at VEGFR, PDGFR and c-Kit(e.g sorafenib,sunitinib,regorafenib)\n\* Any factors that influence the usage of oral administration\n\* Having obvious gastrointestinal hemorrhagic tendency\n\* Known Spinal Cord compression or diseases of brain or pia mater by CT /MRI screening\n\* Organ tumor overloading\n\* Inadequate hepatic, renal, heart, and hematologic functions (hemoglobin \u2264 90g/L, platelets \u2264 100\u00d710\\^9/L, neutrophils \u2264 1.5\u00d710\\^9/L, total bilirubin \u2265 1.25\u00d7the upper limit of normal(ULN), and serum transaminase \u2265 1.5\u00d7ULN (If liver metastases, serum transaminase\u2265 2.5\u00d7ULN), creatinine clearance rate \u2264 60ml/min, cholesterol \u2265 1.5\u00d7ULN and triglyceride\u2265 2.5 x ULN, LVEF: \\< 50%\n\* Preexisting uncontrolled hypertension defined as more than 140/90 mmHg despite using single medical therapy, more than cla ss I (NCI CTCAE 3.0 ) myocardial ischemia, arrhythmia, or cardiac insufficiency\n\* urinary protein\u2265 ++ or 24-hour urinary protein \u2265 1.0 g\n\* Long-term untreated wounds or fractures\n\* Blood coagulation abnormal, having hemorrhagic tendency\n\* Within 1 year before the first treatment occurs artery / venous thromboembolic events, such as cerebral vascular accident (including transient ischemic attack), deep vein thrombosis and pulmonary embolism, etc.\n\* Application of anticoagulants or vitamin K antagonists such as warfarin, heparin or its analogues; If the prothrombin time international normalized ratio (INR) \u2264 1.5, with the purpose of prevention, the use of small doses of warfarin (1mg orally, once daily) or low-dose aspirin (between 80mg to 100mg daily) is allowed\n\* Female: All subjects who are not surgically sterile or postmenopausal must agree and commit to the use of a reliable method of birth control for the duration of the study and for 6 months after the last dose of test article. Child bearing potential, a negative urine or serum pregnancy test result before initiating Famitinib. Male: All subjects who are not surgically sterile or postmenopausal must agree and commit to the use of a reliable method of birth control for the duration of the study and for 6 months after the last dose of test article.\n\* Preexisting thyroid dysfunction, even using medical therapy, thyroid function cannot maintain in the normal range\n\* Abuse of psychiatric drugs or dysphrenia\n\* Less than 4 weeks from the last clinical trial\n\* Ascites need treatment\n\* Immunodeficiency: HIV positive, or other acquired immunodeficiency, congenital immunodeficiency, or organ transplantation\n\* Evidence of significant medical illness that in the investigator's judgment will substantially increase the risk associated with the subject's participation in and completion of the study.",  
 "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 eligibility criteria provided for the clinical trial do not specifically mention a KIT gene mutation as either an inclusion or exclusion criteria. However, there are relevant points to consider:  
  
1. \*\*Exclusion Criterion Related to KIT Targeting\*\*: The exclusion criteria specifically mention prior therapy with tyrosine kinase inhibitors that target VEGFR, PDGFR, and c-Kit (examples include sorafenib, sunitinib, regorafenib). This suggests that if the patient with a KIT mutation has been previously treated with any of these c-Kit targeting agents, they would be ineligible for the trial.  
   
2. \*\*General Inclusion/Exclusion Criteria\*\*: The clinical trial has numerous inclusion and exclusion criteria related to previous treatments, the status of the disease, other medical conditions, and overall fitness level (such as liver function, cardiac function, etc.). It's important for the patient to meet all these criteria regardless of the presence of a KIT mutation.  
  
In conclusion, the presence of a KIT gene mutation alone does not automatically disqualify a patient from the study unless the mutation has led to prior treatment with c-Kit targeting tyrosine kinase inhibitors. Eligibility would depend on the patient's treatment history and their adherence to all other criteria set by the trial. It is advisable for the patient to discuss their specific medical history and any previous treatments with the clinical trial investigators to determine eligibility.