# 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:  
This trial does not explicitly mention KIT gene mutations in its inclusion or exclusion criteria. Therefore, having a KIT mutation \*does not automatically disqualify\* a patient. However, the patient must still meet \*all\* other inclusion criteria and \*none\* of the exclusion criteria to be eligible.