# Clinical Trials Data KIT - Document 4

# A Study of Famitinib in Patients With Advanced or Metastatic Gastroenteropancreatic Neuroendocrine Tumor

## Clinical Trial: https://clinicaltrials.gov/study/NCT01994213

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Unresectable advanced or metastatic, histologically-confirmed, gastroenteropancreatic neuroendocrine tumor. Tumors must be considered well-differentiated grade G1 or grade G2 in accordance with WHO 2010 classification.\n\* Must have at least one measurable disease by RECIST1.1 criteria(tumour lesions \u226510mm in longest diameter, malignant lymph nodes \u226515mm in short axis, scanning layer \u2264 5 mm).\n\* First-line therapy or second-line treatment (second-line treatment i.e. chemotherapy or cytokine therapy as first-line treatment failure or resistant patients).\n\* No previously received targeted therapy of gastroenteropancreatic neuroendocrine tumor (such as everolimus, sunitinib, or other tyrosine kinase or VEGF inhibitor treatment).\n\* Age between 18 and 75 years.\n\* ECOG Performance status \u2264 1.\n\* Ability to understand and the willingness to sign a written informed consent document.\n\nExclusion Criteria:\n\n\* Patients with small-cell carcinoma, pheochromocytoma, paraganglioma or Merkel cell carcinoma\n\* Past or suffering from other cancer, but other than cure basal cell carcinoma and cervical carcinoma in situ\n\* Participated in other clinical trials within four weeks\n\* Concurrent therapy with somatostatin analogs(such as octreotide, lanreotide,etc.)\n\* A variety of factors that affect the oral medication (such as inability to swallow, gastrointestinal resection, chronic diarrhea and intestinal obstruction)\n\* Known brain metastases, spinal cord compression, cancer, meningitis, or screening CT or MRI examination revealed brain or leptomeningeal disease\n\* Subjects received surgery, chemotherapy, radiation therapy, cytokines treatment caused the damage has not been restored, the time interval \u2264 4 weeks, and the wound has not completely healed\n\* Participants have inadequate organ and marrow function as defined below:\n\n \* hemoglobin \\< 90g/L\n \* platelets \\< 100\u00d710\\^9/L\n \* neutrophils \\< 1.5\u00d710\\^9/L\n \* total bilirubin \u2265 1.25\u00d7ULN\n \* serum transaminase(ALT and AST ) \u2265 1.5\u00d7ULN (If liver metastases are present, serum transaminase\u2265 2.5\u00d7ULN)\n \* creatinine clearance rate \u2264 60ml/min\n \* cholesterol \u2265 1.5\u00d7ULN and triglyceride\u2265 2.5 x ULN,\n \* LVEF: \\< 50% by Color Doppler Ultrasonography\n\* Patients with uncontrollable hypertension after using single agent therapy (systolic blood pressure\\> 140 mmHg, diastolic blood pressure\\> 90 mmHg). Patients with more than Class I, myocardial ischemia or myocardial infarction, arrhythmia (including QT interval \u2265 450ms for male and 470ms for female) and class I heart failure.\n\* Urine protein \u2265 + + and confirmed the 24-hour urinary protein\\>1.0 g\n\* Long-term untreated wounds or fractures\n\* Coagulopathy with bleeding tendency (such as active peptic ulcer)\n\* Previous artery / venous thromboembolic events, such as cerebrovascular accident (including transient ischemic attacks), deep vein thrombosis and pulmonary embolism\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 (less than 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\* 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.",  
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"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 is specifically for gastroenteropancreatic neuroendocrine tumors (GEP-NETs). The presence of a KIT gene mutation is not mentioned in the inclusion or exclusion criteria. Therefore, having a KIT mutation \*does not automatically disqualify\* a patient, but it also \*doesn't guarantee eligibility\*.  
  
The patient would need to meet \*all\* other inclusion criteria (such as having a G1 or G2 GEP-NET, specific tumor measurements, etc.) and \*none\* of the exclusion criteria to be eligible. The KIT mutation itself is neither a positive nor a negative factor in this particular trial's eligibility requirements.