# Clinical Trials Data KIT - Document 9

# A Study Of The Efficacy And Safety Of Sunitinib In Patients With Advanced Well-Differentiated Pancreatic Neuroendocrine Tumors

## Clinical Trial: https://clinicaltrials.gov/study/NCT01525550

"description": "EORTC QLQ-GI-NET 21 was a 21-item questionnaire. These 21 questions assesses endocrine symptoms, gastrointestinal (G.I.) symptoms, treatment related symptoms, social functioning, disease related worries, muscle/bone pain, sexual function, information/communication function and body image. Each item was answered on a 4-point scale: 1 =not at all, 2 =a little, 3 =quite a bit, 4 =very much; where higher scores indicated more severe symptoms/problems. Scores averaged, transformed to 0-100 scale; higher score=more severe symptoms.",  
 "eligibilityCriteria": "Inclusion Criteria:\n\n\* Histologically or cytologically proven diagnosis of well-differentiated pancreatic neuroendocrine tumor (according to World Health Organization \\[WHO 2000\\] classification).\n\* Disease progression within 12 months prior to study enrollment.\n\* Disease that is not amenable to surgery, radiation, or combined modality therapy with curative intent.\n\nExclusion Criteria:\n\n\* Patients with poorly differentiated pancreatic neuroendocrine tumors (according to WHO 2000 classification).\n\* Prior treatment with any tyrosine kinase inhibitors, anti vascular endothelial growth factor (VEGF) angiogenesis inhibitors, non VEGF targeted angiogenesis inhibitors, or mammalian target of rapamycin (mTOR) inhibitors.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]  
 "description": "EORTC QLQ-GI-NET 21 was a 21-item questionnaire. These 21 questions assesses endocrine symptoms, gastrointestinal (G.I.) symptoms, treatment related symptoms, social functioning, disease related worries, muscle/bone pain, sexual function, information/communication function and body image. Each item was answered on a 4-point scale: 1 =not at all, 2 =a little, 3 =quite a bit, 4 =very much; where higher scores indicated more severe symptoms/problems. Scores averaged, transformed to 0-100 scale; higher score=more severe symptoms.",

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 clinical trial eligibility criteria provided, whether or not a patient has a KIT gene mutation isn't directly addressed as an eligibility factor. The key inclusion and exclusion criteria for this trial are:  
  
\*\*Inclusion Criteria:\*\*  
- A histologically or cytologically proven diagnosis of well-differentiated pancreatic neuroendocrine tumor.  
- Disease progression within 12 months prior to study enrollment.  
- Disease that is not amenable to surgery, radiation, or combined modality therapy with curative intent.  
  
\*\*Exclusion Criteria:\*\*  
- Patients with poorly differentiated pancreatic neuroendocrine tumors.  
- Prior treatment with specific types of inhibitors such as tyrosine kinase inhibitors, VEGF angiogenesis inhibitors, non-VEGF targeted angiogenesis inhibitors, or mTOR inhibitors.  
  
There is no mention in the criteria of genetic mutations such as a KIT gene mutation, suggesting that the presence of a KIT gene mutation does not alone determine eligibility for this trial. The focus is more on the type and treatment history of the neuroendocrine tumor. Therefore, a patient's eligibility would be determined based on these factors rather than the KIT mutation status specifically. It would be prudent, however, for any patient or provider considering this trial to consult directly with the trial organizers for clarification on individual cases or any additional genetic considerations that may apply.