# Clinical Trials Data KIT - Document 68

# Trial to Assess the Efficacy of Midostaurin (PKC412) in Patients With c-KIT or FLT3-ITD Mutated t(8;21) AML

## Clinical Trial: https://clinicaltrials.gov/study/NCT01830361

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Diagnosis of c-KIT mutated t(8;21) AML i.e.\n\n 1. \\>20% myeloid blasts in bone marrow and/or peripheral blood at initial diagnosis\n 2. Plus cytogenetic diagnosis of aberration t(8;21)/AML1-ETO\n 3. Plus mutation of c-KIT gene (mut-KIT17 or mut-KIT8) or FLT3-ITD mutation or both c-KIT and FLT3-ITD mutations\n\* Chemoresponsive disease as determined by early bone marrow assessment on day 14-16 after first cycle of induction therapy with cytarabine in combination with daunorubicine or idarubicine, or mitoxantrone- Fit for further intensive chemotherapy\n\* Age 18-65 years\n\* ECOG performance status of 0-2\n\* Life expectancy of at least 12 weeks\n\nExclusion Criteria:\n\n\* Primary refractory or previously relapsed AML\n\* Non-eligibility for high-dose cytarabine based consolidation, e.g. intolerance to cytarabine\n\* Inability to swallow oral medications\n\* Symptomatic congestive heart failure\n\* Bilirubin \\>2.5 x upper limit of normal",  
 "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:  
Based on the eligibility criteria provided for the clinical trial, a patient with a KIT gene mutation would be eligible, provided they meet the other inclusion criteria and none of the exclusion criteria. Specifically, the trial requires:  
  
1. A diagnosis of c-KIT mutated t(8;21) AML, which includes:  
 - Greater than 20% myeloid blasts in bone marrow and/or peripheral blood at initial diagnosis.  
 - Cytogenetic diagnosis of aberration t(8;21)/AML1-ETO.  
 - A mutation of the c-KIT gene (mut-KIT17 or mut-KIT8), or an FLT3-ITD mutation, or both c-KIT and FLT3-ITD mutations.  
  
If the patient has a c-KIT mutation, as well as the required cytogenetic profile and disease characteristics, and they fulfill the other inclusion criteria such as being chemoresponsive, being aged 18-65, having an ECOG performance status of 0-2, and having a life expectancy of at least 12 weeks, they would be eligible.  
  
The patient must also not meet any of the exclusion criteria, such as having primary refractory or previously relapsed AML, being non-eligible for high-dose cytarabine-based consolidation, having inability to swallow oral medications, symptomatic congestive heart failure, or elevated bilirubin levels.  
  
If the patient aligns with these requirements, they would be eligible for the trial.