# 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:  
A patient with \*only\* a KIT gene mutation \*without\* the t(8;21) AML translocation would \*not\* be eligible for this trial.  
  
The inclusion criteria specifically require \*both\*:  
  
\* \*\*c-KIT mutated t(8;21) AML:\*\* This means the patient must have the t(8;21) translocation in addition to the KIT mutation.  
\* \*\*>20% myeloid blasts:\*\* Along with the genetic requirements, the patient must have a sufficient blast count.  
  
The presence of a KIT mutation alone does not fulfill the criteria. They must also have the t(8;21) translocation and meet the other inclusion criteria (blast count, chemoresponsive disease, age, ECOG status, life expectancy).