# Clinical Trials Data KIT - Document 40

# Cladribine Plus Pegylated Interpheron Alfa-2a in Systemic Mastocytosis

## Clinical Trial: https://clinicaltrials.gov/study/NCT01602939

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Age older than 18 years.\n\* Diagnosis of advanced systemic mastocytosis (aggressive systemic mastocytosis or proggressing systemic mastocytosis) with D816V or other exon 17 KIT mutations.\n\* ECOG \u2264 3.\n\* Signed informed consent.\n\nExclusion Criteria:\n\n\* Impaired liver function (total bilirubin \u2265 2.0 mg/dl, AST or ALT \\> 3 x upper limit of normal)not related to mastocytosis.\n\* Impaired renal function (\u2265 2.0 mg/dL)not related to mastocytosis.\n\* Grade III-IV cytopenias not related to mastocytosis. Severe cardiopathy (grade III/IV of NYHA, or left ventricular ejection fraction \\< 50%).\n\* Pregnancy or breastfeeding.\n\* Female patients who do not use contraceptive methods.",  
 "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 inclusion criteria provided, a patient with a KIT gene mutation would be eligible for the clinical trial if they have a diagnosis of advanced systemic mastocytosis with D816V or other exon 17 KIT mutations. Therefore, if the patient's KIT mutation is within exon 17, they would meet this particular inclusion criterion.  
  
Additionally, the patient must also meet other inclusion criteria such as being over 18 years old, having an ECOG performance status of 3 or lower, and providing signed informed consent. They must also not meet any of the exclusion criteria, such as impaired liver or renal function not related to mastocytosis, severe cardiopathy, pregnancy or breastfeeding, and some others.