# 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:  
A patient with \*any\* KIT gene mutation including D816V or other exon 17 KIT mutations, would be eligible provided they also meet the other inclusion criteria (over 18, diagnosed with advanced systemic mastocytosis, ECOG ≤ 3, and signed informed consent) and don't meet any of the exclusion criteria. The trial specifically mentions "D816V \*or other exon 17 KIT mutations\*," indicating that mutations other than D816V, as long as they are in exon 17 of the KIT gene, would qualify the patient.