# Clinical Trials Data KIT - Document 55

# Community-based Screening and Treatment of Malaria in Pregnancy: a Cluster-randomized Trial

## Clinical Trial: https://clinicaltrials.gov/study/NCT01941264

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Residence in the study area and intention to stay in the area for the duration of the pregnancy and for delivery.\n\* Aged at least 16 years (pregnant adolescents younger than 16 years will be considered only if they are accompanied by a responsible adult (in the Gambia) or married (considered an adult by marriage in Burkina Faso and Benin.)\n\* Willing to provide biological samples as and when required during the study period (blood and placental biopsy)\n\* Informed consent\n\nExclusion Criteria:\n\n\* A history of sensitivity to sulphonamides.\n\* Already participating in another research study",  
 "healthyVolunteers": true,  
 "sex": "FEMALE",  
 "minimumAge": "16 Years",  
"stdAges": [  
"CHILD",  
"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 provided eligibility criteria for this clinical trial, a patient's eligibility seems to be focused on demographic, residence, and consent-related factors specific to pregnant individuals. The inclusion and exclusion criteria listed do not mention genetic mutations, such as the KIT gene mutation. Therefore, the presence of a KIT gene mutation in a patient would not affect their eligibility to participate in this study, unless additional genetic criteria are specified elsewhere in the trial documentation.  
  
The main criteria for eligibility are:  
  
1. Residence in the study area and intention to remain for the duration of pregnancy and delivery.  
2. Being at least 16 years of age.  
3. Willingness to provide biological samples as required.  
4. Providing informed consent.  
  
Exclusion criteria specifically mention:  
  
1. A history of sensitivity to sulphonamides.  
2. Participation in another research study.  
  
These are the only criteria given, so a KIT gene mutation would not be a factor in deciding eligibility based on the information provided.