# Clinical Trials Data KIT - Document 13

# Environmental Risk Factors for the Anti-synthetase Syndrome

## Clinical Trial: https://clinicaltrials.gov/study/NCT01276470

"eligibilityCriteria": "\* INCLUSION CRITERIA:\n\nThere are no gender or ethnic restrictions to enrollment in the study. Age restrictions for children do apply to enrollment in the study.\n\nThe inclusion criteria for enrollment of myositis subjects are:\n\n1. Diagnosis of myositis based on criteria for possible, probable or definite PM or DM, with or without other connective tissue diseases, documented within 24 months of enrollment (using the most recent diagnosis date to define the 24-month period).\n2. CXR to assess possible ILD and assign the subject to the presumptive anti-synthetase positive or negative category if clinically indicated.\n3. Children must be greater than two years of age.\n4. Able and willing to give informed consent, to complete the questionnaires and to donate blood samples (in case of children greater than 2 years of age but \\<18 years of age, parent/legal guardian must be willing and able to provide informed consent and child will provide assent according to child s maturity level and understanding).\n\nThe exclusion criteria for myositis subjects are:\n\n1. Cancer-associated myositis (cancer diagnosed within 2 years of the diagnosis of myositis).\n2. Inclusion body myositis.\n3. Myositis that has clearly developed as the result of a drug, toxin or other exposure and has resolved after discontinuation of the exposure to that agent.\n4. Children less than 2 years of age.\n\nThe inclusion criteria for controls are:\n\n1. Friends or, if friends are not available, cousins of the anti-synthetase-positive myositis patient, or, if friends or cousins are not available, volunteers from the general community (such as the NIH Normal volunteer program), race- gender- and age- (within 5 years for minors and within 10 years for adults) matched, and when possible who is living as close as possible to the geographic area of the myositis patient.\n2. Controls should be without a recognized autoimmune disease or ILD.\n3. Able and willing to give informed consent, to complete the questionnaires and to donate blood samples (in case of children greater than 2 years of age but \\<18 years of age, parent/legal guardian must be willing and able to provide informed consent) and child will provide assent according to child maturity level and understanding).\n\nThe exclusion criteria for all protocol subjects are:\n\n1. Medical illness that in the judgment of the investigators does not allow safe blood draws or other clinical evaluations needed for study participation.\n2. Cognitive impairment.\n3. Not able or willing to give informed assent or consent.\n4. Children less than 2 years of age.\n5. Patients who at their reference date were not in the US or Canada\n6. Individuals currently incarcerated\n\nHIV considerations:\n\nHIV is not an exclusion for affected participants in this study for the two following reasons:\n\n1. It has no impact on study procedures or tests.\n2. It may be one of the viral risk factors we are investigating.",  
 "healthyVolunteers": true,  
 "sex": "ALL",  
 "minimumAge": "2 Years",  
"stdAges": [  
"CHILD",  
"ADULT",  
"OLDER\_ADULT"  
],  
 "studyPopulation": "General population; There are no gender or ethnic restrictions to enrollment in the study. Age restrictions for children do apply to enrollment in the study.@@@@@@",

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 clinical trial information provided, a patient with a KIT gene mutation would not be explicitly excluded from the trial. The eligibility criteria and exclusion criteria listed are focused on the diagnosis and characteristics related to myositis, autoimmune diseases, and related conditions, but do not mention any specific gene mutations such as KIT. Therefore, as long as the potential participant meets the inclusion criteria for myositis subjects and does not fall under any of the outlined exclusion criteria, they would be considered eligible for the study.  
  
It is important to note that the presence of a KIT gene mutation is not specified in either the inclusion or exclusion criteria, which suggests that it is not a determining factor for eligibility in this trial. However, the final decision would likely depend on the judgment of the investigators and specific details of the patient's medical history.