# Clinical Trials Data KIT - Document 64

# Comparative Study of the Immunogenicity of MMR (Measles, Mumps and Rubella) Single Dose and Multidose Presentations

## Clinical Trial: https://clinicaltrials.gov/study/NCT01777529

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Children of both sexes.\n\* Age between 12 and 23 months and 29 days.\n\* Child in good health, without significant personal morbid history, such as genetic syndromes, epilepsy, diabetes, severe infections and immune dysfunctions.\n\* Concordance of the father or mother, or legal guardian, with the child's participation in the study, and signing the Informed Consent Form (ICF).\n\* Disposition of the father or mother, or legal guardian, to provide name, address, telephone number and other information so you can get in touch with this (s) if necessary.\n\* Responsible able understand the risks of the experiment that, although minimal, there.\n\* Responsible able to understand and sign the informed consent form. If the charge is not able to sign (illiterate) the ICF may be signed by an impartial witness who has followed the whole procedure.\n\* Availability return to collect post-vaccination - The subjects of research may not be participating in another clinical trial during this study.\n\* Not having received the vaccine Immunization Schedule in the last 30 days.\n\* Not receiving another vaccine until harvest 2, 42 days after vaccination with MMR.\n\nNon-inclusion criteria\n\n\* Children with a history of measles, rubella and or mumps.\n\* Having previously received MMR vaccination documented in book (eg in situations of conducting national campaign or blocking vaccination before suspected cases of the disease).\n\* Have received injectable vaccines of live attenuated (eg. Yellow fever vaccine) - in this case, defer vaccination with MMR after 30 days of the last live attenuated vaccine administered.\n\* Having received a transfusion of blood or blood products, including immunoglobulins, less than 1 year.\n\* Skin lesions at sites of venipuncture.\n\* Child subject to abnormal bleeding after injections.\n\* Use the last 6 months in immunosuppressive doses of corticosteroids and other immunosuppressants.\n\* Fever or the day of inclusion in the 3 days prior to the inclusion in this case may be rescheduled for inclusion after 14 days the fever subsides.\n\* Use of antibiotic on the day of inclusion or in the last 7 days prior to the date of inclusion - in this case, may be rescheduled for inclusion after 14 days of the last day of antibiotic use.\n\* Any significant abnormality on physical examination the day of enrollment.\n\* Hypersensitivity known systemic neomycin or any other component of the vaccine.\n\* Guy with a history of severe allergy, anaphylaxis to egg proteins",  
 "healthyVolunteers": true,  
 "sex": "ALL",  
 "minimumAge": "12 Months",  
"stdAges": [  
"CHILD"  
]

Question:  
Based on the following clinical trial information, would a patient with a KIT gene mutation be eligible for the clinical trial?

Answer:  
The inclusion criteria do not mention anything about genetic conditions \*except\* to exclude children with significant personal morbid history, \*such as\* genetic syndromes. A KIT gene mutation can be associated with a variety of conditions, some of which could be considered a "significant personal morbid history" or a "genetic syndrome".  
  
  
Therefore, \*\*it depends on the specific condition associated with the KIT gene mutation\*\*. If the child's KIT mutation results in a clinically significant condition, they would likely be excluded. If the child's KIT mutation does \*not\* result in any significant health problems, they \*might\* be eligible, but it would be up to the investigators to make that determination.