# Clinical Trials Data KIT - Document 48

# Insulin Loaded Orally Dissolved Films (Insulin-ODF)

## Clinical Trial: https://clinicaltrials.gov/study/NCT01446120

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Signed Informed Consent.\n2. 18.5\\<BMI\\<30\n\nExclusion Criteria:\n\n1. Smokers.\n2. Known mouth cavity, gums or gastrointestinal disease.",  
 "healthyVolunteers": true,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT"  
]

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

Answer:  
The provided clinical trial information does not mention any specific exclusion or inclusion criteria related to a KIT gene mutation. The eligibility criteria focus on age, BMI, smoking status, and the presence of mouth, gums, or gastrointestinal diseases. Since a KIT gene mutation is not listed among the exclusion criteria, it is not explicitly a factor for eligibility in this trial.   
  
Therefore, based solely on the information provided, a patient with a KIT gene mutation would be eligible for the clinical trial as long as they meet the other inclusion criteria and do not have any of the listed exclusion criteria. However, it's always important to verify with the clinical trial coordinators for any specific genetic considerations not listed in the basic criteria.