# 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 information doesn't mention KIT gene mutations as either an inclusion or exclusion criterion. Therefore, having a KIT gene mutation \*doesn't automatically disqualify\* the patient. They would need to meet all other inclusion criteria (signed consent, BMI between 18.5 and 30) and not have any of the exclusion criteria (smoker, mouth/gum/GI disease).