# Clinical Trials Data KIT - Document 12

# A Study of Drug Therapies for Salivary Gland Cancers Based on Testing of Genes

## Clinical Trial: https://clinicaltrials.gov/study/NCT02069730

"eligibilityCriteria": "Inclusion Criteria (Phase 1, Molecular Profiling):\n\n\* Have available archival tumor tissue or fresh tumor specimen from diagnostic histological tissue for molecular profiling.\n\* Histological or cytological proof of malignant salivary gland tumor\n\* ECOG performance score 0-2\n\* Documented evidence of recurrent or metastatic disease\n\nInclusion Criteria (Phase 2, Treatment):\n\n\* Interpretable result of molecular profiling in the molecular profiling phase of this study\n\* Advanced recurrent or metastatic salivary gland cancer for which no curative therapy exists\n\* Evidence of clinical or radiological disease progression at the time of study treatment\n\* At least one measurable target lesion as defined by RECIST 1.1\n\* Must have adequate hematological, liver, renal and cardiac function\n\* No concomitant use of drugs which may prolong QTc interval\n\* No history of serious cardiac illness\n\* No serious medical conditions that might be aggravated by treatment or limit compliance.\n\* Central nervous system metastases are permitted provided these are clinically stable\n\* Able to take oral medication and have no evidence of bowel obstruction, infectious/inflammatory bowel disease\n\* No other active malignancy at any other site\n\* 18 years of age or older\n\* Measureable disease as defined by RECIST v1.1\n\* Not receiving any other concurrent investigational agent\n\* If the matched treatment is in the context of another phase I trial, the eligibility criteria of the enrolled trial will be used instead of the criteria from this trial\n\nExclusion Criteria (Phase 1, Molecular Profiling):\n\n\* Refuses to have tumor tissue undergo molecular profiling\n\* Not enough tumor tissue for molecular profiling\n\* Life expectancy less than 3 months\n\nExclusion Criteria (Phase 2, Treatment):\n\n\* Had stopped the previous treatment but showed no clinical or radiological evidence of disease progression\n\* Have received the same drug treatment of assignment to the specific arm before the enrolment in to treatment phase (phase 2)",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"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 the clinical trial, the presence of a KIT gene mutation itself is not explicitly mentioned as either an inclusion or exclusion factor for participation. Instead, the eligibility criteria focus on the type and progression of the cancer, as well as the patient's overall health status and ability to participate in the trial.  
  
To determine if a patient with a KIT gene mutation would be eligible, we would primarily need to look at the phase of the trial they would be entering:  
  
1. \*\*For Phase 1, Molecular Profiling:\*\*  
 - The patient must have malignant salivary gland cancer and tissue available for molecular profiling.  
 - The presence of specific mutations, like KIT, is not a factor in this phase as long as molecular profiling can be performed.  
  
2. \*\*For Phase 2, Treatment:\*\*  
 - The patient must have an interpretable result from the molecular profiling phase and meet several health and disease progression criteria.  
 - If the mutation, such as KIT, leads to a matched treatment in the context of another trial, additional criteria might apply depending on that trial's requirements.  
  
Overall, a patient with a KIT mutation is not inherently disqualified. The key is whether the mutation can be targeted by the available treatment options in the trial. If the trial protocol or treatment arm specifically addresses treatments for KIT-mutated cancers and the patient meets all other criteria, they would likely be eligible for participation. It is best to consult the trial's principal investigator or coordinators for detailed eligibility assessments related to specific mutations like KIT.