# 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:  
The provided information doesn't explicitly state whether a \*specific\* KIT gene mutation is an inclusion or exclusion criteria. The trial requires "molecular profiling" of the tumor. This profiling will determine if the patient's specific molecular profile, including any KIT mutations, matches a treatment arm within the study.  
  
Therefore, simply having a KIT mutation \*does not guarantee\* eligibility. A patient with a KIT mutation \*could\* be eligible if:  
  
1. \*\*They meet all other inclusion criteria:\*\* This includes having adequate organ function, recurrent/metastatic salivary gland cancer, measurable disease, etc.  
2. \*\*Their tumor undergoes molecular profiling:\*\* This is the crucial step.  
3. \*\*The molecular profiling results show a targetable alteration:\*\* The trial likely has specific targeted therapies for certain molecular profiles. The patient's specific KIT mutation (and other genetic alterations) must match a treatment arm within the study for them to be eligible for the treatment phase (Phase 2).  
  
In short, the presence of a KIT mutation isn't inherently disqualifying, but it also doesn't guarantee eligibility. Molecular profiling is required to determine if the specific mutation is relevant to this particular trial.