# Clinical Trials Data EGFR - Document 126

# 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 EGFR gene mutation be eligible for the clinical trial?

Answer:  
This trial has two phases. Phase 1 focuses on molecular profiling of the tumor, and Phase 2 is the actual treatment based on the profiling results.  
  
\*\*Phase 1 Eligibility:\*\*  
  
A patient with an EGFR mutation \*could\* be eligible for the molecular profiling phase if they meet the following:  
  
\* They have sufficient archival or fresh tumor tissue.  
\* They have a confirmed malignant salivary gland tumor.  
\* Their ECOG performance score is 0-2.  
\* They have recurrent or metastatic disease.  
  
The presence of an EGFR mutation itself is \*not\* a requirement or exclusion criterion for Phase 1. The purpose of Phase 1 is to \*determine\* the molecular profile, including whether an EGFR mutation is present.  
  
\*\*Phase 2 Eligibility:\*\*  
  
Whether the patient is eligible for Phase 2 \*depends on the results of the molecular profiling\*. The trial doesn't explicitly state that an EGFR mutation qualifies or disqualifies a patient. It states that the patient must have an "interpretable result of molecular profiling." This suggests that the treatment arm in Phase 2 is based on whatever actionable mutations are found, which \*might\* include EGFR, but could also include other targets.  
  
Therefore, simply having an EGFR mutation doesn't guarantee eligibility for Phase 2. The patient needs to complete Phase 1 profiling, and the resulting molecular profile needs to match one of the treatment arms offered in Phase 2.  
  
In short: An EGFR mutation doesn't automatically exclude a patient, but it also doesn't guarantee inclusion. Eligibility depends on the full molecular profile and the available treatment arms in Phase 2.