# 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:  
Based on the provided eligibility criteria for the clinical trial, there is no specific requirement or exclusion related to an EGFR gene mutation. The focus of the criteria is primarily on the type and stage of cancer (recurrent or metastatic salivary gland cancer), the general health and treatment history of the patient, and the results of molecular profiling.  
  
A patient with a recurrent or metastatic salivary gland tumor and an EGFR gene mutation could potentially be eligible for the Phase 1 molecular profiling if they meet the general inclusion criteria such as having available tumor tissue, adequate performance status, and documented evidence of recurrent or metastatic disease.  
  
To enter Phase 2, the patient would need an interpretable result from molecular profiling and meet additional criteria, including having no curative therapy options, evidence of disease progression, and measurable disease.  
  
Ultimately, whether a patient with an EGFR mutation is eligible would depend on the specific aim and interventions of the trial, especially if a matched treatment targeting EGFR is part of the trial. However, the mutation itself is neither a specified inclusion nor an exclusion criterion, making eligibility dependent primarily on the other outlined conditions.