# Clinical Trials Data EGFR - Document 115

# Study of Nimotuzumab to Treat Esophageal Squamous Cell Carcinoma.

## Clinical Trial: https://clinicaltrials.gov/study/NCT01993784

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Histologically confirmed esophageal squamous carcinoma,failed to first or second line chemothrepay\n\* Age 18 to 75 years old\n\* Measurable disease according to the RECIST criteria(diameter of the lesion should be more than 10mm by spiral CT or MRI, more than 20mm by common CT, the date of image should be less than 15 days before enrollment)\n\* Life expectancy of \u22653 month\n\* Karnofsky performance status \u226580\n\* WBC\\>3,000/mm3, absolute neutrophil count \u22651500/mm3, platelet\\>100,000/mm3, Hb\\>9g/dl\uff0cBilirubin level \\< 1.0 times ULN\uff0cSerum creatinine \\<1.0 times ULN\uff0cALT and AST\\<2.5 times ULN \uff0cAKP \\< 2.5 times ULN \uff0c(\u22645 times ULN in patients with liver metastases)(within 7 days before enrollment)\n\* No sever complication, such as active gastrointestinal bleeding, perforation, jaundice, obstruction, non-cancerous fever\\>38\u2103\uff1b\n\* Normal ECG/cardiac function\n\* Good compliance\n\* Having signed informed consent -\n\nExclusion Criteria:\n\n\* No previous systemic therapy for metastatic esophageal squamous carcinoma\n\* Known hypersensitivity to study drugs\n\* Tumor with length\u226510cm, liver metastasis covers more than 50% of liver,or lung metastasis covers more than 25% of lung\n\* No measurable lesions, eg. pleural fluid and ascites\n\* Only with Other previous malignancy within 5 year, except non-melanoma skin cancer\n\* Heart failure or other sever organ dysfunction, eg. coronary artery disease, myocardial infarction within the last 6 months only Brain or bone metastasis\n\* Chronic diarrhea\n\* Mentally abnormal or disable cognition,including CNS metastasis\n\* Pregnancy or lactation period",  
 "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:  
The eligibility criteria provided for this clinical trial do not explicitly mention the presence or absence of an EGFR gene mutation as a criterion for inclusion or exclusion. Thus, based on the information given, the presence of an EGFR gene mutation would neither automatically include nor exclude a patient from participation.  
  
The main criteria for inclusion focus on having histologically confirmed esophageal squamous carcinoma, previous treatment failure, specific age and performance status, as well as certain measurable lab values and organ function. Exclusion criteria mainly involve prior treatments for metastatic disease, specific tumor metrics, other significant health issues, or recent other malignancies.  
  
If EGFR mutation status is not specified, it likely means it is not a key factor for determining eligibility in this particular trial. However, it is still advisable for the patient or healthcare provider to confirm with the trial coordinators, as there may be specific protocols or undisclosed criteria regarding genetic mutations that are not listed in the public criteria.