# Clinical Trials Data EGFR - Document 29

# Definitive Radiochemotherapy Plus/Minus Cetuximab in Unresectable Locally Advanced Esophageal Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01787006

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Dated and signed written informed consent\n\* Male or female patients between 18 years and 75 years; patients \\> 75 years if their karnofsky performance status is \u2265 80.\n\* Histologically proven squamous cell carcinoma or adenocarcinoma of the esophagus which is not curatively resectable. Resectability has to be defined by a surgeon before radiochemotherapy. The tumor is considered unresectable due to T-stage, N-stage, performance status, nutritional status, co-morbidity (pulmonal function, other), tumor location upper third or other reasons\n\* Karnofsky Performance Status \u2265 70\n\* Women of child-bearing potential must have a negative pregnancy test\n\* Adequate cardial-, pulmonal- and ear function\n\nAdequate bone marrow function:\n\n\* leukocytes \u2265 3.0 x 10\\^9/L\n\* neutrophiles \u2265 1.5 x 10\\^9/L\n\* thrombocytes \u2265 100 x 10\\^9/L\n\* hemoglobin \u2265 10.0 g/dl\n\nAdequate liver function:\n\n\* bilirubin \u2264 2.0 mg/dl\n\* transaminases (serum glutamic pyruvic transaminase (SGPT), serum glutamic oxaloacetic transaminase (SGOT), gamma-GT) \u2264 3 x upper limit of normal (ULN)\n\nAdequate kidney function:\n\n\* serum creatinine \u2264 1.5 mg/dl\n\* creatinine clearance \u2265 50 ml/min according to Cockcroft-Gault Formula\n\* no known allergies against chimeric antibodies\n\* effective contraception for male and female patients if there is a risk of conception\n\nExclusion Criteria:\n\n\* distant metastasis\n\* previous treatment of esophageal cancer\n\* previous therapy with monoclonal antibodies and / or EGFR-targeted therapy\n\* previous second malignancies with exception of a history of a previous curatively treated basal cell carcinoma of the skin or pre-invasive cervix carcinoma\n\* serious concomitant disease or medical condition\n\* lung function: forced expiratory volume in one second (FEV1)) \\< 1.1\n\* clinically relevant coronary artery diseases or known myocardial infarction within the last 12 months or ventricular ejection fraction (LVEF) below normal\n\* every active dermatological condition \\> grade 1\n\* contraindications to receive cisplatin, 5-FU or cetuximab\n\* concurrent treatment with other experimental drugs or participation in another clinical trial within 30 days before study start\n\* patient pregnant or breast feeding\n\* known drug abuse, medication abuse, alcohol abuse\n\* social situations limiting the compliance with the study requirements",  
 "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, a patient with an EGFR gene mutation would not be automatically excluded solely based on the presence of that mutation. The criteria that specifically refer to EGFR relate to previous therapies:  
  
- \*\*Previous therapy with monoclonal antibodies and / or EGFR-targeted therapy\*\* is listed as an exclusion criterion.  
  
However, there is no mention of EGFR mutations themselves being a criterion for exclusion. Therefore, a patient with an EGFR mutation but no prior EGFR-targeted therapy is not excluded from the trial based solely on the mutation.   
  
It's important to review the trial details with a healthcare provider to ensure that all other criteria, both inclusion and exclusion, are carefully considered for eligibility.