# Clinical Trials Data EGFR - Document 104

# Cisplatin and 5-FU +/- Panitumumab for Patients With Nonresectable,Advanced or Metastatic Esophageal Squamous Cell Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01627379

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Signed written informed consent\n2. Male or female \u226518 years of age\n3. Histologically proven squamous cell carcinoma of the esophagus, which is not curatively resectable\\\* or locally recurrent disease and both not eligible\\\*\\\* for definitive radiochemotherapy, or clearly metastatic disease (Tx, Nx, M1, locally unresectable T4, Nx, M0 or TX, N3, M0)\\\* or residual (post-resection) disease not eligible\\\*\\\* for definitive radiochemotherapy\n\n \* resectability has to be defined prior to randomization according to local standards:\n\n The tumor is considered unresectable due to:\n\n T-stage, N-stage, performance status/nutritional status, co-morbidity (pulmonary function, other), tumor location upper third of the esophagus, relation to other organs/structures), patient refusal, other reasons.\n \* eligibility to definitive radiochemotherapy will be determined according to local standards based on the extent of disease, performance status/nutritional status, co-morbidity (pulmonary function, other), volume of neighboring organs within the radiation field, patient refusal, other reasons.\n4. Measurable or non-measurable disease according to RECIST 1.1\n5. ECOG 0-1\n6. Women of child-bearing potential must have a negative pregnancy test\n7. Laboratory requirements\n\n \* Hematology:\n\n \* Absolute neutrophil count \u22651.5x10\\^9/L\n \* Platelet count \u2265100x10\\^9/L\n \* Leukocyte count \u2265 3.0x10\\^9/L\n \* Hemoglobin \u2265 9 g/dL or 5.59 mmol/l\n \* Hepatic Function:\n\n \* Total bilirubin \u2264 1.5 time the upper normal limit (UNL)\n \* AST \u2264 2.5xUNL in absence of liver metastases, or \u22645xUNL in presence of liver metastases\n \* ALT \u2264 2.5xUNL in absence of liver metastases, or \u22645xUNL in presence of liver metastases\n \* Renal Function:\n\n \* Creatinine clearance \u2265 50 mL/min according to Cockroft-Gault formula\n \* Metabolic Function\n\n \* Magnesium \u2265 0.5 mmol/L or 1.2 mg/dL\n \* Calcium \u2265 2 mmol/L or 8.0 mg/dL\n\nExclusion Criteria:\n\n1. Previous chemotherapy of esophageal cancer in the metastatic setting. Previous neoadjuvant chemotherapy or definitive radiochemotherapy with a maximum cumulative dose of 120 mg cisplatin and without recurrence of disease within 4 months after the end of treatment is allowed.\n2. Concurrent radiotherapy involving target lesions used for this study. Concurrent palliative radiation for non-target lesions is allowed if other lesions are available outside the involved field. Previous pre- operative or post-operative radiotherapy is allowed.\n3. Previous exposure to EGFR-targeted therapy\n4. Other previous malignancy with exception of a history of a previous curatively treated basal cell carcinoma of the skin or pre-invasive carcinoma of the cervix or other curatively treated malignant disease without recurrence after at least 5 years of follow-up\n5. Known brain metastases unless adequately treated (surgery or radiotherapy) with no evidence of progression and neurologically stable off anticonvulsants and steroids\n6. Serious concomitant disease or medical condition that in the judgment of the investigator renders the subject at high risk of treatment complication or reduces the probability of assessing clinical effect.\n7. Clinically significant cardiovascular disease (including myocardial infarction, unstable angina, symptomatic congestive heart failure, serious uncontrolled cardiac arrhythmia) \u2264 1 year before enrollment\n8. Inadequate pulmonary function according to the investigator's judgment, history of interstitial lung disease e.g. pneumonitis or pulmonary fibrosis or evidence of interstitial lung disease on baseline chest CT scan.\n9. Hearing loss \u2265 NCI-CTC V.4.03 Grade 3\n10. Subject pregnant or breast feeding, or planning to become pregnant within 6 months after the end of treatment.\n11. Subject (male or female) is not willing to use highly effective methods of contraception (per institutional standard) during treatment and for 6 months (male or female) after the end of treatment.\n12. Contraindications to receive any platin, 5-FU or panitumumab\n13. Concurrent treatment with other experimental drugs or participation in another clinical trial with any investigational drug within 30 days prior to treatment start\n14. Known drug abuse/alcohol abuse\n15. Peripheral polyneuropathy \u2265 NCI-CTC V 4.03 Grade 2\n16. Chronic inflammatory bowels diseases\n17. Social situations limiting the compliance with the study requirements.\n18. History of HIV infection or chonic hepatitis B or C\n19. Concurrent treatment with brivudin or sorivudin or its chemically related analogues. There must be at least a 4-week wash-out period between end of treatment with brivudin, sorivudin or its chemically related analogues and start of therapy with 5-FU.",  
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 "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 information \*\*does not mention EGFR gene mutation status as either an inclusion or exclusion criterion.\*\* Therefore, having an EGFR mutation would \*not automatically disqualify\* a patient, but it also doesn't guarantee eligibility. The patient would need to meet all other inclusion criteria and none of the exclusion criteria to be eligible. Importantly, \*\*previous exposure to EGFR-targeted therapy is an exclusion criterion (Exclusion Criteria #3).\*\* So, if the patient has previously received treatment targeting EGFR, they would be ineligible.