# Clinical Trials Data EGFR - Document 144

# Determination of Cetuximab Versus Cisplatin Early and Late Toxicity Events in HPV+ OPSCC

## Clinical Trial: https://clinicaltrials.gov/study/NCT01874171

"eligibilityCriteria": "Inclusion Criteria:\n\n\* American Joint Committee on Cancer (AJCC) TNM Stage III-IVa (T3N0-T4N0, and T1N1-T4N3) oropharyngeal squamous cell carcinoma (SCC) tumours\n\* Clinical multidisciplinary team decision to treat with primary curative cisplatin chemoradiotherapy\n\* No previous treatment including surgery, except node biopsies or diagnostic tonsillectomy\n\* Medically fit (ECOG 0, 1 or 2)\n\* Adequate cardiovascular, haematological, renal and hepatic function\n\* Age \\> 18 years\n\* Written informed consent given\n\* Using adequate contraception \\[male and female participants\\]. Must take contraceptive measures during, and for at least six months after treatment.\n\nExclusion Criteria:\n\n\* Distant metastasis (i.e. AJCC TNM stage IVc disease)\n\* AJCC TNM Stage T1-2N0 disease\n\* Treated with primary radical surgery to the primary site (e.g. resection)\n\* Concurrent use of CYP3A4 inducers or inhibitors. \\[A standard course of dexamethasone or aprepitant for the prevention of cisplatin-induced nausea and vomiting is permitted\\]\n\* Serious cardiac illness or other medical conditions precluding the use of cisplatin or cetuximab \\[no history of clinically significant cardiac disease, serious arrhythmias, or significant conduction abnormalities; no uncontrolled seizure disorder; no active neurologic disease; no neuropathy greater than grade 1\\]\n\* Patients who have p16+ tumours who also have N2b, N2c or N3 nodal disease and whose lifetime smoking history is also more than 10 pack years (i.e. have both risk factors).\n\* Pregnant or lactating\n\* Previous treatment for any other cancer with cytotoxics, radiotherapy or anti-EGFR therapies\n\* Inadequate renal, haematological or liver functions \\[Absolute neutrophil count \\<1,500/mm3; platelet count \\<100,000/mm3; WBC \\<3,000/mm3; haemoglobin \\<9 g/dL. \\[Haemoglobin correction by transfusion permitted.\\] Bilirubin \\> 1.5 times upper limit of normal (ULN); alkaline phosphatase \\> 2.5 times ULN; AST and ALT \\> 2.5 times ULN. Creatinine \\> 1.5 mg/dL; Creatinine clearance \\< 60 mL/min\\]\n\* Patients with clinically significant hearing impairment\n\* Life expectancy less than 3 months\n\* Other malignancy within the past 3 years except basal cell skin cancer or pre-invasive carcinoma of the cervix.",  
 "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 is specifically for oropharyngeal squamous cell carcinoma (SCC). The inclusion criteria do \*\*not\*\* mention EGFR mutation status as a requirement. The exclusion criteria also do \*\*not\*\* exclude patients based on EGFR mutations. Therefore, having an EGFR mutation \*itself\* does not disqualify a patient.   
  
However, the patient must still meet \*all\* other inclusion criteria and \*not\* meet any of the exclusion criteria to be eligible. Many factors beyond EGFR mutation status are considered.