# 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:  
Based on the provided eligibility criteria for the clinical trial, an EGFR gene mutation is not explicitly mentioned as either an inclusion or exclusion criterion. Therefore, the presence of an EGFR gene mutation alone does not determine eligibility for this clinical trial.  
  
To assess whether a patient with an EGFR gene mutation is eligible, you would need to consider the other specified inclusion and exclusion criteria, such as:  
  
- The patient's cancer stage and diagnosis.  
- Previous treatments received.  
- Their overall medical fitness and function of various organs.  
- Whether they meet other criteria such as age, informed consent, and contraceptive use.  
  
If the patient meets all the inclusion criteria and none of the exclusion criteria, they may be eligible for the clinical trial. However, it may also be advisable to consult with the trial coordinators or a healthcare professional involved in the trial for additional guidance regarding any nuances related to EGFR mutations specifically.