# Clinical Trials Data EGFR - Document 113

# The Role of Positron Emission Tomography (PET) During Erlotinib Treatment for Non-small Cell Lung Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01000428

"eligibilityCriteria": "Inclusion Criteria:\n\n\* \\> 18 years of age\n\* Histologically documented non-small cell lung cancer with metastasis (Stage IV) or locally advanced (Stage IIIB) with malignant effusion.\n\* At least 1 measurable lesion as defined by RECIST. All target lesions must have a unidirectional diameter of at least 1cm. Baseline measurements must be compared within 4 weeks prior to enrollment.\n\* ECOG PS 0-2\n\* At least 3 weeks since the 1st line systemic therapy regimen prior to enrollment. Patients must have recovered to NCI CTCAE v3.0 grade I from all toxicities. But 1st line erlotinib treatment is also allowed.\n\* At least 1 week since the last radiotherapy. Patients must have recovered from all acute toxicities from radiotherapy.\n\* Patients must have adequate hematologic, renal and liver function as defined by Hb \\> 9g/dL, neutrophils \\> 1000/mm3, platelets \\> 50,000/mm3, creatinine \\< 2mg/dL, and AST (SGOT) and/or ALT (SGPT) \\< 5 x UNL (upper normal limit).\n\* Willingness and ability to comply with scheduled visits, treatment plans, laboratory tests and other study procedures.\n\* Written and voluntary informed consent understood, signed and dated.\n\nExclusion Criteria:\n\n\* Prior EGFR TKI treatment.\n\* Symptomatic brain metastasis. Brain metastases stable \\< 2 weeks before dosing or requiring concurrent steroid treatment or with clinical symptoms.\n\* Major surgery within 3 weeks prior to study enrollment.\n\* Previous (less than 3 years ago) or current malignancies at sites other than curatively treated in situ carcinoma of cervix, or basal or squamous cell carcinoma of the skin.\n\* Severe medical illness or active infection that would impair the ability to receive erlotinib.\n\* Pregnancy or breast feeding.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
],  
 "studyPopulation": "Histologically documented non-small cell lung cancer with metastasis (Stage IV) or locally advanced (Stage IIIB) with malignant effusion.",

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 information provided, the clinical trial does not explicitly exclude patients with an EGFR gene mutation. The eligibility criteria mention non-small cell lung cancer (NSCLC) and include allowances for first-line erlotinib treatment, which is often used in the context of EGFR-mutated NSCLC.  
  
However, one key exclusion criterion is prior treatment with an EGFR tyrosine kinase inhibitor (EGFR TKI), which would disqualify a patient. If the patient has not received prior EGFR TKI treatment (such as gefitinib, erlotinib, or osimertinib) as part of their therapy, they would not be excluded based solely on the presence of an EGFR mutation.  
  
To determine eligibility, it is crucial to assess whether the patient meets all inclusion criteria and none of the exclusion criteria. Since the information doesn't mention EGFR mutations specifically, the presence of an EGFR gene mutation alone would not make them ineligible as long as they fulfill all other requirements.