# 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:  
This trial \*\*excludes\*\* patients with prior EGFR TKI treatment. Since EGFR TKIs are specifically designed to target EGFR mutations, it's highly likely that someone with a known EGFR mutation would have already received this type of targeted therapy. Therefore, they would likely be ineligible for this particular trial.