# Clinical Trials Data EGFR - Document 101

# Erlotinib as First-line Treatment of Advanced Non-small Cell Lung Cancer (NSCLC) for Patients Unfit for Chemotherapy

## Clinical Trial: https://clinicaltrials.gov/study/NCT00452075

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Histological or cytological documented diagnosis of inoperable, locally advanced, recurrent or metastatic (Stage IIIB or Stage IV) NSCLC.\n\* Chemo-na\u00efve patients.\n\* Patients who are in the investigator's opinion not medically suitable for chemotherapy.\n\* Measurable disease according to the RECIST criteria.\n\* ECOG performance status of 0 - 3.\n\* Life expectancy of at least 12 weeks.\n\* Patients must be able to take oral medication.\n\* Serum calcium within normal ranges\n\* \u2265 4 weeks since prior surgery or radiation therapy\n\* For all females of childbearing potential a negative pregnancy test must be obtained within 48 hours before starting therapy and must use effective contraception\n\* 18 years of age or older\n\* Written (signed) Informed Consent to participate in the study\n\nExclusion Criteria:\n\n\* Prior systemic antitumor therapy\n\* Any unstable systemic disease which according to the investigator contraindicates the use of the study drug render the subject at high risk from treatment complications (including active infection, unstable angina, myocardial infarction within the previous month, inflammatory bowel disease, hepatic disease with serum bilirubin \u2265 2 upper limit of normal (ULN) or AST and/or ALT \u2265 2 x ULN (or \u2265 5 x ULN if clearly attributable to liver metastasis), renal disease with acute renal failure or serum creatinine \u2265 5 x ULN.\n\* Any other malignancies within 5 years (except for adequately treated carcinoma in situ of the cervix or basal or squamous cell skin cancer).\n\* Nursing mothers or pregnant woman.\n\* Hypersensitivity to Tarceva or co-formulants.\n\* Patients with brain metastasis or spinal cord compression that has not yet been definitively treated with surgery and/or radiation.\n\* Patients with brain metastasis or spinal cord compression that not are in a stable condition despite treatment with steroids.",  
 "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:  
The clinical trial eligibility criteria you provided do not explicitly mention the EGFR gene mutation as either an inclusion or exclusion criterion. Therefore, the presence of an EGFR gene mutation, by itself, does not automatically determine eligibility based on the criteria given.  
  
Eligibility would depend on meeting all the stated inclusion criteria (e.g., diagnosis of inoperable, locally advanced, recurrent, or metastatic NSCLC, chemo-naïve status, ability to take oral medication, ECOG performance status, etc.) and not meeting any of the exclusion criteria (e.g., prior systemic antitumor therapy, unstable systemic disease, etc.).   
  
The presence of an EGFR mutation might not preclude the patient from enrolling, but it is also not listed as a requirement to participate. It would be prudent to consider the specific objectives and interventions of the trial to determine if having an EGFR mutation affects suitability for the study, or to consult with the study investigators for clarification.