# Clinical Trials Data EGFR - Document 94

# Afatinib Plus Nimotuzumb for NSCLC

## Clinical Trial: https://clinicaltrials.gov/study/NCT01861223

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Histologically confirmed diagnosis of stage IIIB or IV NSCLC\n\* Presence of EGFR sensitizing mutations (L858R mutation in exon 21 or exon 19 deletion) or response by RECIST on prior gefitinib or erlotinib or stable disease on prior gefitinib or erlotinib for at least 6 months\n\* Disease progression on treatemtn with gefitinib or erlotinib within 30 days\n\* Biopsy on disease progression\n\* Age \u226520 years\n\* ECOG performance status of 0, 1, or 2\n\* Measurable disease by the criteria of RECIST 1.1\n\* Adequate organ function as evidenced by the following; Absolute neutrophil count \\> 1.5 x 109/L; platelets \\> 100 x 109/L; total bilirubin \u22641.5 UNL; AST and/or ALT \\< 5 UNL; creatinine clearance \u2265 45 mL/min\n\nExclusion Criteria:\n\n\* Known interstitial lung disease\n\* Prior treatment with EGFR targeting antibodies or BIBW 2992\n\* Prior three or more lines of chemotherapy for advanced NSCLC\n\* Significant bowel disease impairing drug absorption\n\* Uncontrolled systemic illness such as DM, CHF, unstable angina, hypertension or arrhythmia\n\* Have symptomatic, untreated, or uncontrolled central nervous system (CNS) metastases. Patients with treated CNS metastases are eligible provided their disease is radiographically stable, asymptomatic, and corticosteroid use has been discontinued for at least 2 weeks prior to the first dose of study drug. Screening of asymptomatic patients without history of CNS metastases is not required.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "20 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, a patient with an EGFR gene mutation would be eligible if they meet the following conditions:  
  
1. They have a histologically confirmed diagnosis of stage IIIB or IV non-small cell lung cancer (NSCLC).  
2. They possess EGFR sensitizing mutations, specifically the L858R mutation in exon 21 or an exon 19 deletion. Alternatively, they could also be eligible if they have shown a response by RECIST criteria on prior treatment with gefitinib or erlotinib, or have stable disease on these drugs for at least 6 months.  
3. They have experienced disease progression on treatment with gefitinib or erlotinib within the last 30 days.  
4. They have undergone a biopsy on disease progression.  
  
Additionally, they must meet the other inclusion criteria (such as age ≥20 years, an ECOG performance status of 0, 1, or 2, measurable disease by RECIST 1.1, and adequate organ function) and none of the exclusion criteria (such as prior treatment with certain drugs, certain medical conditions, or significant bowel disease impairing drug absorption) apply.  
  
If the patient with an EGFR gene mutation meets all of these conditions and none of the exclusion criteria, they would be eligible to participate in this clinical trial.