# 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:  
A patient with an EGFR sensitizing mutation (specifically L858R mutation in exon 21 or exon 19 deletion) \*could\* be eligible for this trial. However, simply having the mutation is not enough. They must ALSO meet \*all\* other inclusion criteria and \*none\* of the exclusion criteria.  
  
Here's a breakdown:  
  
\*\*Potentially Eligible:\*\* The inclusion criteria specifically list "Presence of EGFR sensitizing mutations (L858R mutation in exon 21 or exon 19 deletion)" which directly applies to a patient with an EGFR mutation of the specified types.  
  
\*\*Other Requirements:\*\* Crucially, the patient \*also\* needs:  
  
\* \*\*Stage IIIB or IV NSCLC:\*\* Confirmed by histology.  
\* \*\*Progression after Gefitinib/Erlotinib:\*\* Disease must have progressed on these treatments within 30 days. \*OR\* stable disease on these treatments for at least 6 months. This implies prior treatment with these drugs is required.  
\* \*\*Recent Biopsy:\*\* Taken upon disease progression.  
\* \*\*Age 20 or older.\*\*  
\* \*\*ECOG 0, 1, or 2:\*\* A measure of performance status.  
\* \*\*Measurable Disease:\*\* As defined by RECIST 1.1.  
\* \*\*Adequate Organ Function:\*\* Meeting specific lab value requirements.  
  
\*\*Exclusions:\*\* Even with the mutation and meeting the above, the patient \*cannot\* have:  
  
\* \*\*Interstitial Lung Disease\*\*  
\* \*\*Prior Treatment with certain drugs:\*\* EGFR-targeting antibodies or BIBW 2992.  
\* \*\*Extensive Prior Chemotherapy:\*\* Three or more lines for advanced NSCLC.  
\* \*\*Bowel Disease affecting absorption.\*\*  
\* \*\*Uncontrolled Systemic Illness:\*\* Such as uncontrolled diabetes, CHF, angina, hypertension, or arrhythmia.  
\* \*\*Active CNS Metastases:\*\* Treated CNS metastases are acceptable under certain conditions (stable, asymptomatic, off corticosteroids).  
  
  
In short, while the EGFR mutation is a key requirement, it's just one piece of the puzzle. A full evaluation against all the inclusion and exclusion criteria is needed to determine eligibility.