# Clinical Trials Data EGFR - Document 87

# Phase I Study of the Combination of Afatinib and Ruxolitinib in Patients With Treatment-refractory Non-Small Cell Lung Cancer (NSCLC)

## Clinical Trial: https://clinicaltrials.gov/study/NCT02145637

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Stage 4 NSCLC patients\n2. disease progression after platinum doublet (all), EGFR TKI (if EGFR mutant), and crizotinib (if ALK positive)\n3. Men and women aged 20 years or older\n4. Recovery from previous drug-related toxicity: CTCAE 4.03 \u2264 Grade 1\n5. ECOG 0 or 1\n6. able to orally take and retain drug\n7. have a measurable or unmeasurable lesion under RECIST 1.1 Criteria\n8. have proper hematological, renal, and hepatic functions\n9. intention to use an acceptable contraception\n10. able to read and understand the informed consent form\n\nExclusion Criteria:\n\n1. previous chemotherapy, radiation therapy, immunotherapy, or other anticancer therapy within 14 days\n2. Clinically significant gastrointestinal disorder or malabsorption syndrome\n3. Acute digestive disorder\n4. major organ failure\n5. Significant cardiac disorders\n6. major operation of a main organ in 4 weeks\n7. Untreated symptomatic brain metastasis\n8. pregnant or nursing\n9. previously diagnosed Interstitial lung disease(ILD)\n10. previously treated with irreversible pan-HER inhibitor including Afatinib or Ruxolitinib\n11. previously experienced hypersensitivity to an ingredient of the study drug\n12. must receive CYP3A4 inducer or inhibitor persistently during the study period.\n13. HIV positive or active hepatitis\n14. threatening patient's safety is predicted",  
 "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:  
Potentially yes, but more information is needed.  
  
The inclusion criteria specify "disease progression after... EGFR TKI (if EGFR mutant)". This means a patient \*with\* an EGFR mutation must have had their disease progress \*despite\* being treated with an EGFR Tyrosine Kinase Inhibitor (TKI) therapy. If the patient has an EGFR mutation and \*has not\* received prior TKI therapy, they would \*not\* be eligible for this particular trial. If they \*have\* an EGFR mutation and their disease progressed \*after\* TKI therapy, along with meeting all other inclusion criteria and none of the exclusion criteria, then they \*would\* be eligible.