# Clinical Trials Data EGFR - Document 39

# Icotinib Versus First-line Chemotherapy Plus Maintenance Treatment in EGFR Positive Lung Adenocarcinoma Patients

## Clinical Trial: https://clinicaltrials.gov/study/NCT01719536

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Recurrent or progressive Non-Small Cell Lung Cancer stage IV or IIIB patients.\n\* Positive EGFR Mutation.\n\* No previous systemic anticancer therapy.\n\* Measurable lesion according to RECIST with at least one measurable lesion not previously irradiated, unless disease progression has been documented at that site.\n\* Provision of written informed consent.\n\nExclusion Criteria:\n\n\* Experience of Anti-EGFR(the epidermal growth factor receptor) Monoclonal Antibody or small molecular compounds therapy such as gefitinib, erlotinib or Cetuximab.\n\* Evidence of clinically active Interstitial Lung Diseases (Patients with chronic, stable, radiographic changes who are asymptomatic need not be excluded).\n\* Known severe hypersensitivity to icotinib or any of the excipients of this product.\n\* Evidence of any other significant clinical disorder or laboratory finding that makes it undesirable for the subject to participate in the study.",  
 "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:  
A patient with an EGFR gene mutation \*might\* be eligible. While having a positive EGFR mutation is an inclusion criterion, there are other criteria that must also be met. The patient must \*also\*:  
  
\* Have recurrent or progressive Non-Small Cell Lung Cancer stage IV or IIIB.  
\* Have \*no previous systemic anticancer therapy\*. This is a crucial point.  
\* Have a measurable lesion according to RECIST guidelines.  
\* Have provided written informed consent.  
\* \*Not\* have any of the exclusion criteria (prior anti-EGFR therapy, active interstitial lung disease, hypersensitivity to icotinib, or other significant clinical disorder).  
  
So, simply having the EGFR mutation is not enough. They must fulfill all inclusion criteria and none of the exclusion criteria to be eligible.