# 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:  
Based on the inclusion and exclusion criteria provided for the clinical trial, a patient with an EGFR gene mutation would be eligible if they meet the following conditions:  
  
1. They have recurrent or progressive Non-Small Cell Lung Cancer at stage IV or IIIB.  
2. They have a positive EGFR mutation.  
3. They have not had any previous systemic anticancer therapy.  
4. They have a measurable lesion according to RECIST criteria, with at least one measurable lesion that has not been previously irradiated, unless there is documented disease progression at that site.  
5. They are able to provide written informed consent.  
6. They are at least 18 years old.  
  
Additionally, they should not meet any of the exclusion criteria:  
  
1. They should not have been treated with anti-EGFR therapies such as gefitinib, erlotinib, or cetuximab.  
2. They should not have evidence of clinically active interstitial lung diseases (although asymptomatic chronic, stable radiographic changes do not require exclusion).  
3. They should not have known severe hypersensitivity to icotinib or any of the product's excipients.  
4. They should not have any other significant clinical disorder or concerning laboratory findings that would make participation undesirable.  
  
If a patient with an EGFR mutation meets the inclusion criteria and does not fall under any of the exclusion criteria, they would be eligible for the clinical trial.