# Clinical Trials Data EGFR - Document 111

# GIOTRIF in First Line Therapy of Advanced NSCLC With EGFR-mutations

## Clinical Trial: https://clinicaltrials.gov/study/NCT02047903

"eligibilityCriteria": "Inclusion criteria:\n\n\* EGFR- tyrosine kinase inhibitor (TKI) naive patients with histologically confirmed locally advanced or metastatic NSCLC with activating EGFR-mutations\n\* Age \\>= 18 years\n\* No diagnostic or therapeutic measures beyond routine clinical practice are required\n\* Patients for whom the treating physician has decided to initiate treatment with GIOTRIF\n\* Written informed consent prior inclusion\n\nExclusion criteria:\n\n\* Contraindication for Afatinib according to the Summary of Product characteristics\n\* Participation in another clinical study until 30 days after end of treatment\n\* Prior systemic chemotherapy (Neo-/adjuvant therapy is permitted)\n\* Previous treatment with an EGFR-tyrosine kinase inhibitor\n\* Patients not willing or not able to fill in quality of life questionnaires\n\* Patients with missing or impaired legal capacity\n\* Pregnancy",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
],  
 "studyPopulation": "NSCLC-EGFR mutation positive",

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 for this trial. While the inclusion criteria specify "activating EGFR-mutations," and the study population is "NSCLC-EGFR mutation positive," more information is needed to determine definitive eligibility.  
  
Here's why:  
  
\* \*\*"Activating EGFR-mutations":\*\* Not all EGFR mutations are activating mutations. The trial specifically requires \*activating\* mutations, which are the types that drive cancer growth and are typically targeted by TKIs. A patient needs to have their specific EGFR mutation confirmed as an activating type (like exon 19 deletions or L858R) to be eligible. Simply having \*any\* EGFR mutation is insufficient.  
  
\* \*\*Other criteria:\*\* The patient also needs to meet \*all\* other inclusion criteria (e.g., TKI-naive, age 18 or older, informed consent) and \*none\* of the exclusion criteria (e.g., prior EGFR-TKI treatment, contraindication to Afatinib).  
  
In short, the presence of an EGFR mutation is a necessary but not sufficient condition for eligibility. The specific type of mutation and other inclusion/exclusion criteria must be carefully considered.