# Clinical Trials Data ALK - Document 5

# A Retrospective Study of EGFR-TKIs,Gefitinib, Erlotinib and Osimertinib in NSCLC Patients Treatment

## Clinical Trial: https://clinicaltrials.gov/study/NCT01994057

"eligibilityCriteria": "Inclusion Criteria:\n\nThe main patient entry criteria included: age\u2265 18 years ; histologically and cytologically proved NSCLC; Eastern cooperative oncology group performance status (ECOG PS)\u22642; adequate hematological , renal, and hepatic functions. Exclusion Criteria:\n\nuncontrolled systemic disease ,any evidence of clinically active interstitial lung diseases, and other chemotherapy at the time of inclusion. The protocol was approved by the Ethical Committee of Cancer Center of Sun Yat-Sen University (CCSU), and written informed consent was obtained form each patient.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
],  
 "studyPopulation": "locally advanced or metastatic NSCLC (non-small cell lung cancer) patients; administrated with gefitinib,erlotinib .",

Question:  
Based on the following clinical trial information, would a patient with a ALK gene mutation be eligible for the clinical trial?

Answer:  
Based on the provided eligibility criteria, there is no specific mention of ALK gene mutation status as an inclusion or exclusion factor for this clinical trial. The criteria focus on:  
  
- Adult patients (age ≥ 18 years)  
- Diagnosis of non-small cell lung cancer (NSCLC), histologically or cytologically proven  
- ECOG performance status of 2 or less  
- Adequate hematological, renal, and hepatic functions  
- No uncontrolled systemic disease, clinically active interstitial lung diseases, or concurrent chemotherapy at the time of inclusion  
- Treatment with gefitinib or erlotinib  
  
Since an ALK gene mutation is not explicitly listed as a requirement or a disqualification, a patient with an ALK mutation might still be eligible, provided they meet all other inclusion criteria and do not meet any exclusion criteria. However, it would be essential to confirm this with the trial organizers, as ALK mutation status might still indirectly influence eligibility based on treatment plans or other unpublished criteria.