# Clinical Trials Data ALK - Document 1

# Genetics of EGFR (Epidermal Growth Factor Receptor) Mutation Study

## Clinical Trial: https://clinicaltrials.gov/study/NCT01838577

"eligibilityCriteria": "\* Histologically or cytologically diagnosed NSCLC, all histologies are acceptable.\n\* Patients can be included in the study with any disease stage and at any time during the disease course.\n\* Any type (surgery, RadioTherapy, chemotherapy, targeted agents) of previous treatment and any line of treatment are eligible.\n\* Age \u226518 years.\n\nAbsence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol; those conditions should be discussed with the patient before registration in the trial.\n\nBefore patient registration, written informed consent must be given according to ICH/GCP (International Conference on Harmonisation/Good Clinical Practice), and national/local regulations.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
],  
 "studyPopulation": "Case cohort: Patients with proven EGFR mutation in exons 18-21 from tumor material.\n\nControl cohort: Patients known to be somatic EGFR \"wild-type,\" i.e. no mutation detected in exons 18-21 from tumor material.",

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 clinical trial eligibility criteria you provided, a patient with an ALK gene mutation would not be eligible for this trial. The study population specifically includes:  
  
- A case cohort of patients with a proven EGFR mutation in exons 18-21 from tumor material.  
- A control cohort of patients known to be somatic EGFR "wild-type," meaning no mutation detected in exons 18-21 from tumor material.  
  
The criteria focus solely on the EGFR gene mutations or the absence of these mutations (wild-type). There is no mention of ALK gene mutations in the study population or eligibility criteria. Therefore, a patient with an ALK gene mutation does not fit into either the case or control cohort definitions and thus would not be eligible for this trial.