# Clinical Trials Data EGFR - Document 33

# De Novo Resistance to Epidermal Growth Factor Receptor-Tyrosine Kinase Inhibitors

## Clinical Trial: https://clinicaltrials.gov/study/NCT01697163

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Pathologically proven unresectable NSCLC\n2. 20 years of age or older\n3. Planned treatment with Iressa\u00ae\n4. Patients with activating EGFR mutation (del 19, L858R)\n5. Available detailed smoking history\n6. Available tissue samples (archival tissue) for mutational or molecular analysis (representative paraffin block or unstained sections from tumor diagnostic specimen are mandatory)\n7. Available blood sample\n8. At least one lesion that is measurable according to the RECIST 1.1 criteria by CT or MRI\n9. Written informed consent\n\nExclusion Criteria:\n\n1. More than 3rd line treatment\n2. Previously treated with other EGFR-TKI\n3. Life expectancy of less than 12 weeks\n4. Pregnant or lactating female\n5. Any unresolved toxicity greater than CTC grade 2 (version 4.0) from previous anti cancer treatment.\n6. Unsuitable patient in this treatment as determined by doctor.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "20 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
],  
 "studyPopulation": "NSCLC patient with EGFR mutation",

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 provided eligibility criteria, a patient with an EGFR gene mutation would be eligible for the clinical trial if they meet the following conditions:  
  
- They have a pathologically proven unresectable non-small cell lung cancer (NSCLC).  
- They are 20 years of age or older.  
- They have a planned treatment with Iressa® (gefitinib).  
- They have an activating EGFR mutation, specifically either a deletion 19 mutation or an L858R mutation.  
- They have available detailed smoking history.  
- They can provide available tissue samples (archival tissue) for mutational or molecular analysis.  
- They can provide an available blood sample.  
- They have at least one lesion that is measurable according to RECIST 1.1 criteria by CT or MRI.  
- They can provide written informed consent.  
  
However, they must not meet any of the exclusion criteria:  
  
- More than 3rd line treatment.  
- Previously treated with other EGFR-TKI.  
- Life expectancy of less than 12 weeks.  
- Being pregnant or lactating.  
- Having any unresolved toxicity greater than CTC grade 2 from previous anti-cancer treatment.  
- Being deemed unsuitable for the treatment by a doctor.  
  
If the patient with the EGFR mutation fits all the inclusion criteria and none of the exclusion criteria, they would be eligible for the clinical trial.