# 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:  
A patient with an activating EGFR mutation \*specifically\* a deletion in exon 19 (del 19) or a specific point mutation causing a leucine-to-arginine substitution at codon 858 (L858R) would be eligible. The criteria explicitly states "Patients with activating EGFR mutation \*\*(del 19, L858R)\*\*". Other EGFR mutations, even if considered "activating," would \*not\* qualify the patient for this particular trial.