# Clinical Trials Data EGFR - Document 81

# High-Dose,Pulsatile Erlotinib/Gefitinib for Advanced NSCLC Patients After Failure of Standard Dose EGFR-TKIs

## Clinical Trial: https://clinicaltrials.gov/study/NCT01965275

"eligibilityCriteria": "Inclusion Criteria:\n\n\* 1. NSCLC patients were confirmed by histology or cytology 2. Patients were ever treated with standard dose EGFR-TKIs(Erlotinib or Gefitinib )on which he/she achieved complete remission/partial remission,or maintained stable disease for 4 months.Disease progression at present (accord to RECISTv1.1 criteria\uff09 3.At least one target lesion that has not previously been radiated and is measurable according to RECIST v1.1; 4.Have an ECOG PS of 0-2 5.At least 8 weeks of expected survival time 6.Have no serious cardiovascular,hepatobiliary or renal disorders 7.Provision of a voluntarily given, personally signed and dated, written informed consent document 8.Must be in accordance with the following laboratory biochemical data: Hgb\u226580g/L\uff0cWBC\u22653.0\u00d710\\^9/L\uff0cANC\u22651.0\u00d710\\^9/L\uff0c PLT\u226580\u00d710\\^9/L Renal function\uff1aSCr\u2264ULN Liver function\uff1a if no hepatic metastases:AST/ALT\u22642.5ULN if hepatic metastases:AST/ALT\u22645ULN\n\nExclusion Criteria:\n\n\* If the subject meet any of the following exclusion criteria ,he/she is no eligible to participate in this study\n\n 1. Have chronic toxicity reaction(above grade 2) and not recovered( hair loss not include)\n 2. Have Appeared skin rashes or diarrhea(above grade 3),or have any reason lead to decrement during standard dose EGFR-TKIs treatment\n 3. Female subjects who are in pregnancy or lactation\uff0cor of childbearing age but don't take any contraceptive measures\n 4. Current enrollment in another therapeutic clinical study\n 5. Have any symptoms of brain metastases or leptomeningeal metastases\n 6. Subjects will not be eligible if they have history of prior malignancy in past 5 years\n 7. Any psychiatric or cognitive disorder that would limit the understanding or rendering of informed consent and/or compromise compliance with the requirements of this study or known drug abuse/alcohol abuse.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

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

Answer:  
The eligibility criteria mention that patients should have NSCLC (Non-Small Cell Lung Cancer) and have been previously treated with standard dose EGFR-TKIs (Epidermal Growth Factor Receptor - Tyrosine Kinase Inhibitors). While many NSCLC patients \*do\* have EGFR mutations, having the mutation is not explicitly stated as an inclusion criterion. Therefore, simply having an EGFR mutation doesn't automatically qualify a patient. They must meet \*all\* other inclusion criteria and \*none\* of the exclusion criteria to be eligible.