# 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:  
Based on the provided clinical trial information, a patient with an EGFR gene mutation would be eligible to participate in this trial if they meet the inclusion criteria and do not meet any of the exclusion criteria.  
  
Here's why such a patient might be eligible:  
  
- The inclusion criteria specify that NSCLC (non-small cell lung cancer) patients must have been treated with standard dose EGFR-TKIs (Erlotinib or Gefitinib), which are typically used for NSCLC patients with EGFR mutations.  
- The trial requires that the patients must have achieved a complete remission/partial remission, or maintained stable disease for 4 months with the EGFR-TKI treatment, which would imply that they have benefited from the EGFR-targeted therapy. This directly relates to having an EGFR mutation as these drugs are specifically effective in such cases.  
  
Assuming the patient meets all other inclusion criteria and none of the exclusion criteria apply (such as not having severe treatment side effects, no history of certain other medical conditions, etc.), then a patient with an EGFR mutation would indeed be eligible for this clinical trial.