# Clinical Trials Data EGFR - Document 143

# Afatinib Expanded Access Program

## Clinical Trial: https://clinicaltrials.gov/study/NCT01649284

"eligibilityCriteria": "Inclusion criteria:\n\nPatients with:\n\n1. locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC)\n2. Epidermal Growth Factor Receptor (EGFR) mutation-positive result per the institution's testing methodology.\n3. male or female patients age \\>=18 years\n4. Adequate organ function, defined as all of the following:\n\n 1. Left Ventricular Ejection Fraction (LVEF) \\>50% or within institution normal values\n 2. Absolute Neutrophil Count (ANC) \\> 1500/mm3.\n 3. Platelet count \\>75,000/mm3\n 4. Serum creatinine \\< 1.5 times of the upper limit of normal\n 5. Total Bilirubin \\< 1.5 times upper limit of (institutional) normal.\n 6. Aspartate Amino Transferase (AST) or Alanine Amino Transferase (ALT) \\< three times the upper limit of (institutional) normal (ULN).\n5. ECOG score between 0 - 2\n6. written informed consent by patient or guardian prior to admission into the trial that is consistent with International Conference on Harmonisation (ICH)- Good Clinical Practice (GCP) guidelines and local law.\n\nExclusion criteria:\n\nPatients who or with:\n\n1. hormonal anti-cancer treatment within 2 weeks prior to start of trial treatment (continued use of anti-androgens and/or gonadorelin analogues for treatment of prostate cancer permitted)\n2. Radiotherapy within 14 days prior to drug administration, except as follows:\n\n 1. Palliative radiation to organs other than chest may be allowed up to 2 weeks prior to drug administration, and\n 2. Single dose palliative treatment for symptomatic metastasis outside above allowance to be discussed with sponsor prior to enrolling.\n3. major surgery within 4 weeks before starting trial treatment or scheduled for surgery during the projected course of the trial\n4. known hypersensitivity to afatinib or any of its excipients\n5. history or presence of clinically relevant cardiovascular abnormalities such as uncontrolled hypertension, congestive heart failure New York Heart Association (NYHA) classification of 3, unstable angina or poorly controlled arrhythmia as determined by the treating physician. Myocardial infarction within 6 months prior to starting trial treatment.\n6. are Women of Child-Bearing Potential (WOCBP) and men who are able to father a child, unwilling to be abstinent or use adequate contraception prior to trial entry, for the duration of trial participation and for at least 2 weeks after treatment has ended.\n7. childbearing potential who are: a) are nursing or b) are pregnant or c) are not using an acceptable method of birth control, or do not plan to continue using this method throughout the trial and/or do not agree to submit to pregnancy testing required by this protocol\n8. any history of or concomitant condition that, in the opinion of the treating physician, would compromise the patient's ability to comply with the trial or interfere with the evaluation of safety for the trial drug\n9. previous or concomitant malignancies at other sites, except effectively treated non-melanoma skin cancers, carcinoma in situ of the cervix, ductal carcinoma in situ or effectively treated malignancy that has been in remission for more than 3 years and is considered to be cured.\n10. requiring treatment with any of the prohibited concomitant medications listed in Section 4.2.2 of the protocol that can not be stopped for the duration of trial participation\n11. known pre-existing interstitial lung disease\n12. presence of poorly controlled gastrointestinal disorders that could affect the absorption of the trial drug based on treating physician assessment.\n13. active hepatitis B infection, active Hepatitis C (HEP C) infection and/or known Human Immunodeficiency Virus (HIV) carrier.\n14. meningeal carcinomatosis\n15. symptomatic brain metastases (patients with asymptomatic brain metastases, who were previously treated, are eligible provided they have had Stable Disease (SD) for at least 4 weeks on stable doses of medication)",  
 "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:  
A patient with an EGFR gene mutation \*could\* be eligible for this trial, provided they also meet \*all\* of the other inclusion criteria and \*none\* of the exclusion criteria. Having the EGFR mutation is only one requirement. They must also, for example:  
  
\* Have locally advanced or metastatic NSCLC.  
\* Be 18 years or older.  
\* Have adequate organ function (as defined in the criteria).  
\* Have an ECOG score between 0 and 2.  
\* Not have any of the listed exclusion criteria (e.g., recent hormonal anti-cancer treatment, uncontrolled cardiovascular abnormalities, active hepatitis B or C infection).  
  
  
It's crucial to remember that simply having the EGFR mutation isn't a guarantee of eligibility. A physician would need to evaluate the patient's complete medical history and current condition to determine their final eligibility.