# Clinical Trials Data EGFR - Document 19

# Lapatinib and Bortezomib in Patients With Advanced Malignancies

## Clinical Trial: https://clinicaltrials.gov/study/NCT01497626

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Histologically proven malignant solid tumor with measurable disease\n\* Progression on, or intolerance of, or ineligibility for all standard therapies\n\* Biopsy accessible tumor deposits\n\* LVEF \\>/= institutional normal\n\* Corrected QT interval less than 500 milliseconds by EKG\n\* ECOG performance status 0-2\n\* Subjects with no brain metastases or a history of previously treated brain metastases who have been treated by surgery or stereotactic radiosurgery at least 4 weeks prior to enrollment and have a baseline MRI that shows no evidence of active intercranial disease and have not had treatment with steroids within 1 week of enrollment.\n\* Adequate hepatic, bone marrow, and renal function\n\* Partial thromboplastin time must be \\</= 1.5 x upper limit of institution's normal range and INR \\< 1.5. Subjects on anticoagulants will be permitted to enroll as long as the INR is in the acceptable therapeutic range.\n\* Life expectancy \\> 12 weeks\n\* Women of childbearing potential must have a negative serum pregnancy test within 14 days prior to initiation of treatment and/or postmenopausal women must be amenorrheic for at least 12 months.\n\* Subject is capable of understanding and complying with parameters as outlines in the protocol and able to sign and date the informed consent form.\n\nExclusion Criteria:\n\n\* Patients with lymphomas\n\* CNS metastases which do not meet the criteria outlines in the inclusion criteria\n\* Peripheral neuropathy \\>/= Grade 2 at baseline or peripheral neuropathy \\>/= Grade 1 with neuropathic pain\n\* Active severe infection or known chronic infection with HIV or hepatitis B virus\n\* Cardiovascular disease problems including unstable angina, therapy for life-threatening ventricular arrhythmia, or myocardial infarction, stroke, or congestive heart failure within the last 6 months\n\* Life-threatening visceral disease or other severe concurrent disease\n\* Women who are pregnant or breastfeeding\n\* Anticipated patient survival under 3 months\n\* Concurrent use of known CYP 3A4 inhibiting or activating medications",  
 "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 information provided doesn't explicitly state that having an EGFR mutation is an \*inclusion\* criteria. Therefore, simply having an EGFR mutation doesn't automatically qualify a patient. They must \*also\* meet \*all\* other inclusion criteria and \*not\* meet any of the exclusion criteria.  
  
If the patient with the EGFR mutation also has, for example, active severe infection or uncontrolled CNS metastases, they would be excluded despite having the mutation. Conversely, a patient \*without\* an EGFR mutation could still be eligible if they meet all other inclusion and exclusion criteria. More information is needed about the specific patient's condition to determine eligibility.