# 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:  
Based on the provided eligibility criteria, there is no explicit exclusion relating to an EGFR gene mutation. The key eligibility considerations seem to focus on the type and status of the tumor, previous treatments, and overall health factors such as cardiovascular and infection status, rather than specific genetic mutations like EGFR.  
  
If a patient with an EGFR gene mutation meets all the other inclusion criteria and none of the exclusion criteria, they would likely be eligible to participate in the clinical trial. It would be essential, however, to ensure all other clinical aspects are in line with the trial’s requirements and to confirm with the study coordinators if there are any additional genetic-specific criteria not mentioned here.