# Clinical Trials Data EGFR - Document 38

# Concentration and Activity of Lapatinib in Vestibular Schwannomas

## Clinical Trial: https://clinicaltrials.gov/study/NCT00863122

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Meet diagnostic criteria for NF2 including presence of bilateral VS or idiopathic VS without evidence of genetic syndrome.\n\* VS surgery determined clinically necessary by the treating physician and scheduled within 4 weeks.\n\* Normal cardiac left ventricular ejection fraction (LVEF) by multiple-gated acquisition (MUGA) scan or transthoracic echocardiogram.\n\* Karnofsky performance status 60% (i.e. the patient must be able to care for himself/herself with occasional help from others).\n\* Must have the following hematologic, renal and liver function: Absolute neutrophil count \u2265 1,000/mm\u00b3 (unsupported); platelet count \u2265 75,000/mm\u00b3 (unsupported); hemoglobin \u2265 8 g/dL (transfusion support allowed); Creatinine \u2264 1.5 times upper limit of normal (ULN) OR glomerular filtration rate \u2265 70 ml/min; Bilirubin \u2264 1.5 times ULN; ALT \u2264 2.5 times ULN.\n\* Be able to provide written informed consent.\n\* Any neurologic deficits must be stable for \u2265 1 week.\n\* Be able to swallow tablets.\n\* Subjects with the potential for pregnancy or impregnating their partner must agree to follow acceptable birth control methods to avoid conception. Women of childbearing potential must have a negative pregnancy test.\n\* Suspend the use of P450 inducing or P450 suppressing agents for a minimum of 10 days prior to starting lapatinib.\n\nExclusion Criteria:\n\n\* Serious concurrent infection or medical illness, which would jeopardize the ability of the patient to receive the treatment outlined in this protocol with reasonable safety.\n\* Pregnant or breast-feeding.\n\* Receiving concurrent therapy for their tumor (i.e. chemotherapeutics or investigational agents, radiation or immunotherapy) within 4 weeks of the first dose of the study drug.\n\* Concurrent or prior malignancy, other than curatively treated carcinoma-in-situ or basal cell carcinoma of the skin. Subjects who have been free of disease (any prior malignancy) for five years are eligible for this study.\n\* Received cytochrome P450-inducing anticonvulsants (EIADs; e.g., phenytoin, carbamazepine, phenobarbital, primidone, oxcarbazepine) or similar agents (e.g., rifampin) or P450 inhibiting agents (Ketoconazole, Itraconazole, Clarithromycin, Atazanavir, Indinavir, Nefazodone, Nelfinavir, Ritonavir, Saquinavir, Telithromycin, Voriconazole) within 10 days prior to starting lapatinib.\n\* Significant gastrointestinal disorder(s)(e.g., Crohn's disease, ulcerative colitis, extensive gastric resection).\n\* Neurologic deficits that are rapidly progressing.\n\* Known cardiac disease (either arrhythmia or congestive heart failure) requiring treatment.",  
 "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:  
This trial is for patients with Neurofibromatosis 2 (NF2), characterized by bilateral vestibular schwannomas (VS). The eligibility criteria mention nothing about EGFR gene mutations. Therefore, having an EGFR mutation does \*not\* automatically qualify or disqualify a patient. They would still need to meet all other inclusion criteria and not have any of the exclusion criteria.