# Clinical Trials Data ERBB2 - Document 3

# 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 ERBB2 gene mutation be eligible for the clinical trial?

Answer:  
Based on the provided eligibility criteria for this clinical trial, there is no specific mention of an ERBB2 gene mutation affecting eligibility. The criteria seem focused on the diagnosis of NF2 (Neurofibromatosis Type 2), the necessity for VS (Vestibular Schwannoma) surgery, and meeting several other health and treatment history conditions. Factors such as cardiac health, hematologic and renal function, as well as medication history, are also considered.  
  
Since an ERBB2 gene mutation is not specified in the inclusion or exclusion criteria, a patient with this mutation would not be automatically ineligible. Eligibility would depend more on whether the patient meets all the listed inclusion criteria and none of the exclusion criteria rather than the presence of an ERBB2 mutation. However, it would still be advisable for the patient to discuss their specific genetic mutation and any related health considerations with the clinical trial coordinators or their healthcare provider to confirm eligibility.