# Clinical Trials Data ERBB2 - Document 31

# T-DM1 With Abraxane and Lapatinib for Metastatic HER2 Positive Breast Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT02073916

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Documented metastatic Her2 over-expressed breast cancer.\n\* Age \u2265 18 years Patients must have received at least two prior therapies for their malignant disease.\n\* Patients must have \\< Grade 2 pre-existing peripheral neuropathy (per CTCAE)\n\* Adequate organ function (cardiac ejection fraction of \u2265 45%),\n\* CBC not less than .75 of institutional lower limit.\n\* Patients must have adequate liver function: AST and ALT \\< 2.5 X upper limit of normal, alkaline phosphatase \\< 2.5 X upper limit of normal, unless bone metastasis is present in the absence of liver metastasis Bilirubin \\< 1.5 mg/dL\n\* Patients must have adequate renal function: creatinine \\<1.5 mg/dL is recommended; however, institutional norms are acceptable.\n\* Negative serum or urine \u03b2-hCG pregnancy test at screening for patients of childbearing potential\n\* Fertile patients must use effective contraception (barrier method - condoms, diaphragm - also in conjunction with spermicidal jelly, or total abstinence. Oral, injectable, or implant hormonal contraceptives are not allowed). Contraception method must be used during treatment and for three months after completing treatment Signed informed consent form (ICF)\n\nExclusion Criteria:\n\n\* Any medical or psychiatric condition that would prevent informed consent or limit survival to less than 4 weeks.\n\* Absolute QT interval of \\>460 msec in the presence of potassium \\>4.0mEq/L and Magnesium \\>1.8mg/dl.\n\* Patient with HIV and post- transplant associated lymphoproliferative disorders.\n\* Patient with concurrent use of complementary or alternative medicines that would confound the interpretation of toxicities and antitumor activity of Trastuzumab Emtansine, Lapatinib or Abraxane.\n\* Pregnant or lactating women.\n\* Concurrent treatment with an investigational agent or participation in another therapeutic clinical trial\n\* Known immediate or delayed hypersensitivity reaction or idiosyncrasy to drugs chemically related to trastuzumab Emtansine, lapatinib, abraxane, or their components.\n\* Malabsorption syndrome, disease significantly affecting gastrointestinal function, or resection of the stomach or small bowel.\n\* Subjects with ulcerative colitis are also excluded.",  
 "healthyVolunteers": false,  
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"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 eligibility criteria provided for the clinical trial, a patient with an ERBB2 gene mutation would likely be eligible, as long as the mutation results in Her2 over-expressed breast cancer. The inclusion criteria list the need for "documented metastatic Her2 over-expressed breast cancer," which typically involves changes or amplifications in the ERBB2 gene that lead to Her2 protein overexpression.  
  
The patient would also need to meet additional requirements such as age, prior therapy history, pre-existing conditions, organ function, contraception usage, and consent capabilities as stated in the inclusion criteria. They should not have any conditions listed in the exclusion criteria that would prevent participation.  
  
Therefore, having an ERBB2 mutation per se does not exclude the patient from this trial; it may support their eligibility if it correlates with Her2 overexpression. It's important to ensure they meet all other specified criteria and do not fall under any exclusion conditions.