# Clinical Trials Data EGFR - Document 100

# Pre Operative Trastuzumab in Operable Breast Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01785420

"eligibilityCriteria": "Inclusion Criteria:a.\n\n1. Female subjects aged 18 years or older.\n2. Histologically and/or cytologically confirmed diagnosis of breast cancer. Clinical stages breast cancer: HER2 positive, T1 or T2 or T3, N0 or N1, resectable T4, or resectable N2, (all M0)\n3. Documentation of erbB-2 gene amplification by FISH (as defined by a ratio \\>2.2) or chromogenic in situ hybridization (CISH, as defined by the manufacturer's kit instruction) or documentation of erbB-2-overexpression by IHC (defined as IHC3+, or IHC2+ with FISH or CISH confirmation) based on local laboratory.\n4. LVEF within institutional range of normal as measured by MUGA or ECHO.\n5. Screening laboratory values within the following parameters:\n\n 1. Absolute neutrophil count (ANC) \u22651.5 x 109 /L (1500/mm3)\n 2. Platelet count \u2265100 x 109/L (100,000/mm3)\n 3. Hemoglobin \u22659.0 g/dL (90 g/L)\n 4. Serum creatinine \u22641.5 x upper limit of normal (ULN)\n 5. Total bilirubin \u22641.5 x ULN (\\<3 ULN if Gilbert's disease) 6Aspartate aminotransferase (AST) and/or alanine aminotransferase (ALT)\n\n \* 2.5 x ULN\n\nExclusion Criteria:\n\n1. Bilateral breast cancer\n2. Active uncontrolled cardiac disease, including cardiomyopathy, CHF (New York Heart Association \\[NYHA\\] functional classification of \u22653), unstable angina, and myocardial infarction (within 12 months of study entry).\n3. Inadequately controlled hypertension (ie, systolic blood pressure \\[BP\\] \\> 180 mm Hg or diastolic BP \\> 100 mm Hg).\n4. Family history of congenital long or short QT syndrome, Brugada syndrome or QT/QTc interval \\> 0.45 second or known history of QT/QTc prolongation or torsade de pointe (TdP).\n5. Significant chronic gastrointestinal disorder with diarrhea as a major symptom (eg, Crohn's disease, malabsorption, or grade \u22652 diarrhea of any etiology at baseline).\n6. Women who are pregnant, breast-feeding.",  
 "healthyVolunteers": false,  
 "sex": "FEMALE",  
 "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 clinical trial eligibility criteria provided, a patient with an EGFR gene mutation is not directly addressed as either an inclusion or exclusion criterion. The trial's inclusion criteria focus on female patients with HER2-positive breast cancer, diagnosed through erbB-2 gene amplification or overexpression, and having certain health and laboratory parameters within specified ranges.  
  
As EGFR mutations are not mentioned in either the inclusion or exclusion criteria, it seems that an EGFR gene mutation would not affect eligibility per the information provided. However, eligibility could be further confirmed by consulting with the trial coordinators, as they can provide more specific guidance on any additional factors that might influence eligibility.  
  
There might also be considerations regarding overall treatment compatibility based on other specific genomic profiles or treatment regimens the patient may have undergone due to the EGFR mutation, but the trial criteria alone do not exclude patients based on EGFR status.