# Clinical Trials Data ERBB2 - Document 48

# Role of Early Versus Late Switch to Lapatinib-Capecitabine (TYCO)

## Clinical Trial: https://clinicaltrials.gov/study/NCT01160094

"eligibilityCriteria": "\* Women with ErbB2+ MBC (ErbB2 expression confirmed by immunohistochemistry or FISH/CISH, either in the primary tumor or in the metastasis, according to the institution's common practice);\n\* Older than 18 years old;\n\* Have received prior treatment with trastuzumab-containing regimen for ErbB2+ breast cancer;\n\* Progressing after trastuzumab-containing regimen either used for the treatment of metastatic disease or progressing after adjuvant /neoadjuvant trastuzumab treatment;\n\* Eligible to start standard treatment with Lapatinib-capecitabine at conventional doses, OR receiving standard treatment with\n\* Lapatinib-capecitabine at conventional doses, for no longer than 10 weeks from the start of the treatment to the date of inclusion in the study;\n\* Signed consent to participate and release information for this study.",  
 "healthyVolunteers": false,  
 "sex": "FEMALE",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
],  
 "studyPopulation": "All cases of ErbB2 positive metastatic breast cancer, receiving approved standard treatment with lapatinib-capecitabine, after trastuzumab-containing regimen progression in community setting. Patients from private and public settings.",

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 clinical trial eligibility criteria provided, a patient with an ERBB2 (ErbB2) gene mutation would be eligible for this trial if they meet the following conditions:  
  
1. \*\*ERBB2 Positive Metastatic Breast Cancer\*\*: The patient must have ErbB2+ metastatic breast cancer (MBC), which suggests overexpression or amplification of the ERBB2 gene confirmed by immunohistochemistry, FISH, or CISH.  
   
2. \*\*Prior Treatment\*\*: The patient must have received a prior treatment regimen containing trastuzumab for ErbB2-positive breast cancer and must have shown disease progression after this treatment, whether it was used for metastatic disease or after adjuvant/neoadjuvant therapy.  
  
3. \*\*Current or Planned Treatment\*\*: The patient should be eligible for, or already receiving (for no more than 10 weeks before study inclusion), standard treatment with Lapatinib-capecitabine at conventional doses.  
  
4. \*\*Age and Gender\*\*: The trial is open to women 18 years or older.  
  
5. \*\*Informed Consent\*\*: The patient must sign the consent to participate in the study.  
  
If the patient meets all these specific criteria, they would be eligible for the clinical trial.