# 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:  
A patient with an ERBB2 (HER2) gene mutation \*could\* be eligible, but the criteria specify ERBB2 \*expression\* confirmed by IHC or FISH/CISH. Having the gene mutation doesn't automatically guarantee overexpression of the protein, which is what these tests determine.  
  
So, if the patient's tumor shows ERBB2 overexpression by IHC or FISH/CISH, and they meet all the other criteria (female, over 18, prior trastuzumab treatment, progression after trastuzumab, eligible for or recently started on lapatinib-capecitabine, and signed consent), then they would likely be eligible. They should consult with their oncologist and the trial investigators to confirm.