# Clinical Trials Data ERBB2 - Document 37

# Myocet, Docetaxel & Trastuzumab as 1st Line Treatment of Patients With HER-2/Neu Positive Metastatic Breast Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT00250874

"eligibilityCriteria": "Inclusion Criteria:\n\n\* HER-2/neu overexpression assessed by FISH test or with immunohistochemical methods: Dako(the result must be 3+ with dakotest); if the immunohistochemical test results 2+ it is needed a positive FISH test\n\* Female \\< 70yrs\n\* Histologically or cytologically proven breast cancer.\n\* Metastatic or locally advanced breast cancer (clinical stage: III-IV)\n\* Adequate hematological, hepatic, renal and cardiac function, the latter confirmed by echocardiography with FEVS \u226550%\n\* Prior adjuvant chemotherapy if doxorubicin total dose \u2264300 mg/m2, epirubicin total dose \u2264450 mg/m2\n\nExclusion Criteria:\n\n\* History of cardiopathy\n\* Severe hepatic and renal diseases\n\* Brain metastases as the only parameter of disease\n\* Contraindication to the use of corticosteroids as premedication\n\* Acute infectious diseases\n\* Insulin-dependent diabetes\n\* History of other cancers except for adequately treated basal cell skin cancer or in situ carcinoma of the cervix\n\* Concurrent treatment with any other cancer therapy",  
 "healthyVolunteers": false,  
 "sex": "FEMALE",  
 "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:  
This trial requires \*\*HER-2/neu overexpression\*\*, not specifically an ERBB2 gene mutation. While ERBB2 (also known as HER2) mutations can \*lead\* to overexpression, they are not the same thing. The trial specifies very particular methods for confirming overexpression (FISH or IHC with specific scoring criteria using the Dako test).  
  
Therefore, a patient with an ERBB2 mutation would \*\*only be eligible if that mutation results in HER-2/neu overexpression as confirmed by the specific tests and scoring criteria outlined in the inclusion criteria.\*\* Simply having the mutation is not sufficient for enrollment.