# Clinical Trials Data ERBB2 - Document 62

# IMaging PAtients for Cancer Drug selecTion - Metastatic Breast Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01957332

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Patient with first presentation of MBC, regardless of ER and HER2 status of the primary tumor, who is eligible for first-line systemic therapy.\n\* Patient with non-rapidly progressive MBC, not requiring urgent initiation of chemotherapy, based on clinician's evaluation which may include:\n\n \* no recent (\\< 2 weeks prior to screening visit) significant worsening of MBC related signs and symptoms according to patient history.\n \* in case of liver metastases: no significant increase in liver function tests alanine aminotransferase aspartate transaminase (ASAT) and alanine transaminase (ALAT) in 2 weeks prior to screening visit. (Significant increase of liver function test is defined as 50% increase of absolute amount of ASAT/ALAT.)\n\* Patients in whom standard imaging work-up of MBC was recently (\u2264 28 days) performed. Standard imaging must include: CT chest/abdomen, 18F-FDG-PET and bone scintigraphy.\n\* Patient with measurable or clinically evaluable (bone only) disease on recent standard work up of MBC are eligible.\n\* Metastatic lesion(s) of which a histological biopsy can safely be obtained according to standard clinical care procedures.\n\* Primary tumor blocks available for confirmatory central laboratory ER/HER2 testing in the UMCG. If available a snap frozen sample of the primary tumor will also be centralized in the University Medical Center Groningen (UMCG).\n\* WHO performance status 0-2.\n\* Patient is able to undergo PET imaging procedures.\n\* Age \\>18 years of age, willing and able to comply with the protocol as judged by the investigator.\n\* Signed written informed consent.\n\nExclusion Criteria:\n\n\* Contraindications for systemic treatment (as will be assigned based on biopsy and experimental scan results), either chemotherapy, hormonal therapy or anti-HER2 therapy, based on clinical judgment of treating medical oncologist and patient history.\n\* Pregnant or lactating women.\n\* Prior allergic reaction to immunoglobulins or immunoglobulin allergy.\n\* Inability to comply with study procedures.\n\* Rapidly progressive (visceral) disease requiring rapid initiation of chemotherapy.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "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:  
Based on the eligibility criteria provided for the clinical trial, a patient with an ERBB2 (HER2) gene mutation could be eligible. The inclusion criteria state:  
  
- The patient can have MBC (Metastatic Breast Cancer) regardless of ER (Estrogen Receptor) and HER2 status. This implies that HER2 (ERBB2) positive status does not disqualify the patient.  
  
This means that having an ERBB2 gene mutation would not automatically exclude the patient from the trial. The key factors for eligibility will instead depend on other clinical factors such as:  
  
- The overall presentation of the metastatic breast cancer.  
- The need for first-line systemic therapy.  
- The absence of rapidly progressive disease.  
- The ability to provide necessary biopsy and imaging, among others.  
  
Unless there are other exclusion factors related to the specific treatment being tested, it seems that an ERBB2 mutation alone would not make the patient ineligible for this trial. However, confirmation from the trial's investigators or a careful review of any treatment-specific criteria might be necessary to ensure eligibility.