# 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:  
The information provided states that patients with \*\*first presentation of MBC (metastatic breast cancer), regardless of ER and HER2 status of the primary tumor\*\*, are eligible. Therefore, a patient with an ERBB2 (HER2) gene mutation \*\*would be eligible\*\* for this trial based on that criterion alone.  
  
However, they must \*also\* meet all other inclusion criteria and \*not\* meet any exclusion criteria. The ERBB2 mutation status itself doesn't disqualify them.