# Clinical Trials Data EGFR - Document 149

# 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 EGFR gene mutation be eligible for the clinical trial?

Answer:  
Based on the provided clinical trial eligibility criteria, there is no mention of exclusion related specifically to the presence of an EGFR gene mutation. The criteria focus on the presentation and progression of metastatic breast cancer (MBC), patient performance status, and other health-related exclusions such as contraindications for systemic treatment, pregnancy, or allergies to specific substances.  
  
Therefore, an EGFR gene mutation alone would not make a patient ineligible for this clinical trial unless it somehow results in the patient meeting one of the other exclusion criteria, such as contraindications for certain treatments. As always, it is recommended for the patient and their healthcare provider to discuss the specific details of the trial eligibility with the study coordinators to ensure that all criteria are considered.