# 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:  
The provided information doesn't explicitly exclude patients with EGFR mutations. A patient with an EGFR mutation \*could\* be eligible if they meet \*all\* of the other inclusion criteria and \*none\* of the exclusion criteria.  
  
Here's why it's not a simple yes or no:  
  
\* \*\*Eligibility depends on other factors:\*\* The trial focuses on first-line systemic therapy for metastatic breast cancer (MBC). While EGFR mutations are more common in lung cancer, they can occur in breast cancer. The key is whether the patient's overall condition and disease progression align with the trial's specific requirements.  
\* \*\*Biopsy Results are Crucial:\*\* The criteria mention "Contraindications for systemic treatment (as will be assigned based on biopsy and experimental scan results)." The type of systemic therapy planned based on the biopsy (which could potentially target the EGFR mutation) will determine eligibility. If the EGFR mutation makes standard treatments unsafe or ineffective, the patient might be excluded.  
\* \*\*"Rapidly progressive disease" is a key factor:\*\* If the EGFR mutation is driving aggressive disease progression requiring immediate chemotherapy, the patient would be excluded.  
  
\*\*In summary:\*\* An EGFR mutation itself doesn't automatically disqualify a patient. A detailed assessment by the treating oncologist is necessary to determine eligibility based on the complete clinical picture, including the biopsy results and the nature of the EGFR mutation's impact on the patient's cancer.