# Clinical Trials Data ERBB2 - Document 25

# Study of Biomarker Profiles in Asia Pacific erb2+/HER2 Breast Cancer Patients Treated With Lapatinib

## Clinical Trial: https://clinicaltrials.gov/study/NCT01248897

"eligibilityCriteria": "Inclusion Criteria:\n\n1. HER2-positive (defined as either (a) IHC3+ or (b) FISH+ in local lab) recurrent / metastatic breast cancer patients who have received treatment with lapatinib-based regimen. These are either new, current or completed cases from any of the following settings:\n\n \* treated according to physician's clinical judgement in routine practice; or\n \* treated in clinical trials with known allocation to lapatinib-based regimen; or\n \* treated via lapatinib expanded access or named patient programs. These regimens should contain lapatinib as the only anti-HER2 agent.\n2. Exposed to \\< 2 lines of trastuzumab-based regimen in the metastatic setting prior to start of lapatinib-based regimen. These regimens should contain trastuzumab as the only anti-HER2 agent.\n3. Patients with an historical tumor biopsy specimen available from their primary breast cancer diagnosis. If this is not available, then at least a specimen should be available anytime during the period before the patient started on any anti-HER2 therapy.\n4. Willing to give written informed consent to release the tumor biopsy specimen with corresponding clinical data. If consent could be waived according to institutional practice (eg. patient already deceased, or patient previously provided blanket consent for institution to utilize tissue/data for research purpose), this is accepted with appropriate supporting documentation.\n\nExclusion Criteria:\n\n1. Patients who have been exposed to other experimental anti-HER2 therapy eg. pertuzumab, trastuzumab-DM, neratinib, ertumaxomab, AV-412, BIBW2992, CUDC-101, anti-HER2 vaccines.\n2. Other primary lesions that are not of breast origin.",  
 "healthyVolunteers": false,  
 "sex": "FEMALE",  
"stdAges": [  
"CHILD",  
"ADULT",  
"OLDER\_ADULT"  
],  
 "studyPopulation": "Asia Pacific erb2+/HER2 Breast Cancer Patients",

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 clinical trial information provided, the eligibility for the trial is primarily based on HER2 status and prior treatment history. The trial specifically mentions inclusion criteria for HER2-positive breast cancer patients, which is determined by either IHC3+ or FISH+ assays, indicating overexpression or amplification of the HER2 protein.  
  
The ERBB2 gene, also known as HER2, is responsible for the production of the HER2 protein. Therefore, if a patient has an ERBB2 gene mutation that results in HER2 positivity (such as overexpression or amplification), they would meet the HER2-positive criteria part of the inclusion.  
  
Additional inclusion factors include prior treatment with lapatinib-based regimens and limited exposure to trastuzumab-based regimens in the metastatic setting, among others.  
  
The exclusion criteria mention prior exposure to certain experimental anti-HER2 therapies and indicate that patients cannot have primary lesions not of breast origin.  
  
In summary, if a patient with an ERBB2 gene mutation exhibits HER2 positivity according to the defined criteria (IHC3+ or FISH+), and meets other listed inclusion and exclusion criteria, they would be eligible to participate in this clinical trial.