# Clinical Trials Data ERBB2 - Document 45

# A Feasibility Study for Women Receiving Anthracycline Chemotherapy With or Without Radiation for HER2-neu Positive Invasive Ductal Carcinoma

## Clinical Trial: https://clinicaltrials.gov/study/NCT02156648

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Stage I-III, HER2-neu positive invasive ductal carcinoma\n2. Scheduled to receive adjuvant/neo-adjuvant 5-Fluorouracil, Epirubicin, Cyclophosphamide and Docetaxel (FEC-D) chemotherapy\n3. Scheduled to receive adjuvant Trastuzumab\n4. ECOG Performance status 0-2\n5. Adequate baseline imaging on transthoracic echocardiography, and baseline cardiac ejection fraction of \u2265 55%. Additionally, breast cancer patients\u226545 years of age and scheduled to receive whole breast radiation therapy will receive two cardiac PET scans.\n\nExclusion Criteria:\n\n1. Prior anthracycline chemotherapy\n2. History of dilated cardiomyopathy, congestive heart failure, or coronary artery disease\n3. Life expectancy less than 15 months\n4. Pregnant or lactating women\n5. Use of beta receptor antagonists, calcium channel antagonists, angiotensin converting enzyme inhibitors, or angiotensin receptor inhibitors at baseline.\n6. Previous chest wall/breast or nodal radiation.",  
 "healthyVolunteers": false,  
 "sex": "FEMALE",  
 "minimumAge": "19 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:  
A patient with an ERBB2 (also known as HER2) gene mutation \*could\* be eligible for this trial, but more information is needed. Here's why:  
  
\* \*\*Positive:\*\* The inclusion criteria specifically state "HER2-neu positive invasive ductal carcinoma." ERBB2 is the gene that codes for HER2, so a mutation in this gene is what leads to HER2-positive breast cancer. This is a key requirement for the trial.  
  
\* \*\*Uncertainties:\*\* We don't know the patient's:  
 \* \*\*Cancer stage:\*\* The trial requires Stage I-III.  
 \* \*\*Planned treatment:\*\* The trial requires patients scheduled for FEC-D chemotherapy and adjuvant Trastuzumab.  
 \* \*\*ECOG Performance status:\*\* This needs to be 0-2.  
 \* \*\*Cardiac function:\*\* The patient needs adequate baseline imaging and ejection fraction ≥ 55%. Additional cardiac PET scans are required for patients ≥45 years old receiving whole breast radiation.  
 \* \*\*Other medications:\*\* The exclusion criteria list several medications that would disqualify the patient.  
 \* \*\*Prior treatments:\*\* Prior anthracycline chemotherapy or chest wall/breast/nodal radiation would exclude the patient.  
 \* \*\*Life expectancy, pregnancy/lactation status:\*\* These are also factors in eligibility.  
  
\*\*In short:\*\* The ERBB2 mutation makes the patient a \*potential\* candidate, but a full assessment based on all the inclusion and exclusion criteria is necessary to determine definitive eligibility.