# Clinical Trials Data ERBB2 - Document 60

# A Retrospective Study of Biomarkers in Non-Small Cell Lung Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01100840

"briefSummary": "The purpose of this study is:\n\n1. To characterize the types and frequency of molecular alterations to the epidermal growth factor receptor (EGFR) pathway, FGFR4 and EML-ALK in Asian patients with non-small cell lung cancer\n2. To identify candidate biomarkers of importance in the EGFR and estrogen pathways\n\nMost, if not all, human malignancies including lung cancer are caused by somatic alterations of the genome, leading to activation of oncogenes or inactivation of tumor suppressor genes and their resultant oncogenic effects. In addition to mutations, increased chromosomal copy number (by amplification or polysomy) and DNA methylation are other mechanisms of oncogene activation and tumour suppressor gene inactivation respectively.\n\nLittle is known about the relationship between these oncogenes of the EGFR family and the recently described oncogenes FGFR4 and fusion gene EML4-ALK. Recent data suggests molecularly defined subgroups of non-small cell lung cancer (NSCLC) exist and can be used to predict for sensitivity to targeted agents (erlotinib or gefitinib) or cytotoxic chemotherapy (pemetrexate, gemcitabine, platinum agents). The findings that estrogen receptors are present in lung tumours and that estrogen can stimulate growth and proliferation of lung cancers in vitro and in vivo are provocative. Further studies to evaluate the role of estrogens and other sex hormones in lung cancer are warranted.\n\nA further understanding of the molecular indicators of lung cancer prognosis and treatment prediction would improve drug development and patient treatment selection.\n\nArchived paraffin-embedded and fresh frozen NSCLC tumor tissue will be obtained via the Department of Pathology and the National University Tissue Repository respectively. Clinico-pathological characteristics will be obtained from the case records, Pathology and Tissue Repository. DNA will be isolated using standard techniques. Sequencing of genes in the EGFR signaling pathway: EGFR, KRAS, ErbB2, ErbB3, MET, PI3K, and BRAF as well as FGFR4. Unstained slides from the paraffin-embedded tissue will be obtained and subjected to fluoresce in vitro hybridization (FISH) for breakpoints in the EML4 and ALK genes as previously described. For cases that have been snap-frozen, RNA will be extracted and EML4-ALK fusions will be confirmed using RT-PCR and pre-specified primers. To analyse the expression of proteins of putative relevance to EGFR function (such as EGFR, ErbB2, ErbB3, AKT, MET, STAT, ERK, MAPK, cyclin D1, C/EBPa), downstream effects of EGFR: cell proliferation (Ki-67), angiogenesis (CD34, VEGF-A), apoptosis (bcl-2), metastasis, and hormonal influence (oestrogen and progesterone receptors, aromatase), TMA technology will be utilised. The status of the tumor suppressor genes PTEN and C/EBPa will be analysed."  
 "eligibilityCriteria": "Inclusion Criteria:\n\n\* Nil\n\nExclusion Criteria:\n\n\* Nil",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
"stdAges": [  
"CHILD",  
"ADULT",  
"OLDER\_ADULT"  
],  
 "studyPopulation": "Archived paraffin-embedded and fresh frozen NSCLC tumor tissue will be obtained via the Department of Pathology at Tan Tock Seng Hospital and National University Hospital and the National University Tissue Repository respectively. Clinico-pathological characteristics will be obtained from the case records, Pathology and Tissue Repository.",

Question:  
Based on the following clinical trial information, would a patient with a ERBB2 gene mutation be eligible for the clinical trial?

Answer:  
Yes, a patient with an ERBB2 (also known as HER2) mutation would likely be eligible for this study. Here's why:  
  
\* \*\*Study Purpose:\*\* The study aims to characterize molecular alterations in several pathways, \*including\* the EGFR pathway. ERBB2 is part of the EGFR family. The study specifically mentions sequencing of the \*ErbB2\* gene.  
\* \*\*Inclusion/Exclusion Criteria:\*\* The provided criteria state "Nil" for both inclusion and exclusion, meaning there are no specific requirements or restrictions for participation based on particular mutations. This implies that any patient with NSCLC tumor tissue available (as specified in the study population) is eligible.  
  
Therefore, as long as the patient has NSCLC and the required tissue samples can be obtained, the presence of an ERBB2 mutation would not disqualify them. In fact, it makes them a relevant subject for the study's investigation into EGFR pathway alterations.