# Clinical Trials Data EGFR - Document 52

# Laboratory-Treated Autologous Lymphocytes, Aldesleukin, and GM-CSF in Treating Patients With Recurrent, Refractory, or Metastatic Non-Small Cell Lung Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT00569296

"eligibilityCriteria": "DISEASE CHARACTERISTICS:\n\n\* Histologically or cytologically confirmed non-small cell lung cancer (NSCLC)\n\n \* Recurrent, refractory, or metastatic disease after \u2265 1 prior first-line regimen (chemotherapy or radiotherapy)\n\* Documented EGFR-positive disease (any expression level) by immunohistochemistry (IHC) (may be based on archival sample)\n\* Measurable or evaluable disease by radiograph, CT scan, MRI, and/or physical exam\n\* Appropriate slides of the primary lesion must be available for review of IHC staining assessment by a central pathology team\n\* No clinical evidence of active brain metastases\n\n \* Patients with brain metastases are eligible provide they have received definitive radiotherapy or chemotherapy and/or have undergone surgical resection for brain metastases\n\* No prior hematological malignancy\n\nPATIENT CHARACTERISTICS:\n\n\* Karnofsky performance status (PS) 60-100% OR ECOG PS 0-2\n\* Life expectancy \u2265 3 months\n\* Not pregnant or nursing\n\* Negative pregnancy test\n\* Fertile patients must use effective contraception\n\* Granulocytes \u2265 1,000/mm\\^3\n\* Platelet count \u2265 50,000/mm\\^3\n\* Hemoglobin \u2265 8 g/dL\n\* BUN \u2264 2.0 times normal\n\* Serum creatinine \u2264 2.0 mg/dL\n\* Bilirubin \u2264 1.5 times normal\n\* SGOT \u2264 1.5 times normal (with or without liver metastases)\n\* Hepatitis B surface antigen and HIV negative\n\* LVEF \u2265 45 % at rest (by MUGA)\n\n \* No evidence of depressed left ventricular function\n\* FEV\_1, DLCO, and FVC \u2265 50% of the predicted value\n\* No other malignancy, except for the following:\n\n \* History of curatively treated in situ squamous cell carcinoma or basal cell carcinoma of the skin\n \* History of other curatively treated malignancy (except those with a hematologic origin) for which the patient has remained in complete remission \\> 5 years after completing therapy (as documented by history, physical exams, tumor markers, and radiology scanning)\n\* No serious medical or psychiatric illness that would preclude giving informed consent or receiving intensive treatment\n\* No recent myocardial infarction (within the past year)\n\* No current angina/coronary symptoms requiring medications\n\* No clinical evidence of congestive heart failure requiring medical management (irrespective of MUGA results)\n\* No systolic blood pressure (BP) \u2265 130 mm Hg or diastolic BP \u2265 80 mm Hg\n\n \* Patients with elevated BP must have it controlled by anti-hypertensive medications for at least 7 days prior to the first infusion\n\nPRIOR CONCURRENT THERAPY:\n\n\* See Disease Characteristics\n\* More than 4 weeks since prior chemotherapy or radiotherapy\n\* At least 4 weeks since prior cetuximab or small molecule EGFR-inhibitors including, but not limited to, gefitinib or erlotinib hydrochloride\n\* No concurrent radiotherapy\n\* No concurrent steroids except for treatment of adrenal failure, septic shock, or pulmonary toxicity or hormones for non-disease-related conditions (e.g., insulin for diabetes)",  
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"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 eligibility criteria specifically states: "Documented EGFR-positive disease (any expression level) by immunohistochemistry (IHC)". Therefore, a patient with an EGFR gene mutation \*\*might\*\* be eligible. However, simply having an EGFR gene mutation isn't sufficient. The mutation must result in EGFR-positive disease as determined by an immunohistochemistry (IHC) test. The trial requires documentation of this positive IHC result. If the patient has an EGFR mutation but doesn't have a positive IHC result, they would not be eligible.