# 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)",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
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"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:  
Based on the eligibility criteria for the clinical trial you provided, a patient with an EGFR gene mutation would be eligible to participate in the trial. The eligibility criteria specifically mention that the disease must be "EGFR-positive" as documented by immunohistochemistry (IHC), indicating that expression of EGFR is a requirement for inclusion. It doesn't specify the type of EGFR mutation, so any level of expression is considered sufficient as long as it can be documented.  
  
However, it's important to ensure that the patient meets all other specified eligibility criteria, including disease characteristics, patient characteristics, and prior/concurrent therapy conditions. If the patient meets these criteria, including documented EGFR-positive disease, they would be eligible for the clinical trial.