# Clinical Trials Data EGFR - Document 46

# CMV-specific Cytotoxic T Lymphocytes Expressing CAR Targeting HER2 in Patients With GBM

## Clinical Trial: https://clinicaltrials.gov/study/NCT01109095

"eligibilityCriteria": "INCLUSION CRITERIA:\n\n\* Histopathological verification of glioblastoma multiforme (GBM: WHO grade IV) with recurrent or progressive disease after front line therapy.\n\* HER2 positive GBM\n\* CMV seropositive\n\* Normal ECHO (Left ventricular ejection fraction (LVEF) has to be with in normal, institutional limits)\n\* Life expectancy 6 weeks or greater\n\* Karnofsky/Lansky score 50 or greater\n\* Patient or parent/guardian capable of providing informed consent\n\* Bilirubin 3x or less than normal, AST 5x or less than normal, creatinine 2x normal or less for age and Hgb 9.0 g/dl or more; WBC greater than 2,000/ul; ANC greater than 1,000/ul; platelets greater than 100,000/ul\n\* Pulse oximetry 90% or more on room air\n\* Sexually active patients must be willing to utilize one of the more effective birth control methods for 6 months after the CTL infusion. The male partner should use a condom.\n\* Available autologous HER2.CAR-transduced CMV-specific cytotoxic T lymphocytes with 15% or greater expression of HER2.CAR determined by flow-cytometry and killing of HER2-positive targets 20% or more in cytotoxicity assay.\n\* Recovered from the acute toxic effects of all prior chemotherapy at least 4 weeks before entering this study. One exception is Temozolomide(TMZ), an alkylation agent used as a radiosensitizer and adjuvant chemotherapeutic agent for GBM. Due to the extremely short half life of TMZ, patients will be allowed to continue receiving it up to two days prior to cell infusion and cannot restart until six weeks after the infusion.\n\nEXCLUSION CRITERIA:\n\n\* Severe intercurrent infection\n\* Known HIV positivity\n\* Pregnant or lactating\n\* History of hypersensitivity reactions to murine protein-containing products",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
"stdAges": [  
"CHILD",  
"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, the presence of an EGFR gene mutation is not listed as either an inclusion or exclusion criterion. Here is a summary of the key eligibility points from the provided criteria:  
  
### Inclusion Criteria:  
- Patients must have recurrent or progressive glioblastoma multiforme (GBM).  
- The GBM must be HER2 positive.  
- Patients must be CMV seropositive.  
- Other inclusion criteria include normal cardiac function, life expectancy, performance score, blood work parameters, and requirements around consent and contraception.  
  
### Exclusion Criteria:  
- Severe infection, known HIV positivity, pregnancy, lactation, or hypersensitivity to murine proteins.  
  
An EGFR mutation is not mentioned, so having such a mutation would neither automatically include nor exclude a patient from participating. However, the key determinants for eligibility appear to be based on the condition of HER2-positive GBM and other specific medical and demographic criteria.  
  
Therefore, generally speaking, a patient with an EGFR gene mutation may still be eligible for the trial if they meet all the other inclusion criteria and none of the exclusion criteria, assuming their GBM is HER2 positive and they fulfill other study-specific requirements. It would be best to consult with a healthcare provider or the trial investigators for a definitive eligibility determination.