# Clinical Trials Data EGFR - Document 25

# Anti-CD3 x Anti-Erbitux® Armed Activated T Cells (Phase Ib) for Gastrointestinal (GI Cancer)

## Clinical Trial: https://clinicaltrials.gov/study/NCT01420874

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Histological or cytological proof of colorectal or pancreatic adenocarcinoma\n\* Must have metastatic colorectal cancer or pancreatic cancer with stable disease after first line chemotherapy or patients with colorectal or pancreatic cancer who have progressed with standard chemotherapy options\\\*\n\* Standard chemotherapy for metastatic colorectal cancer include 5-FU/capecitabine with either oxaliplatin or irinotecan based regimen with or without bevacizumab or cetuximab.\n\* Standard chemotherapy for metastatic pancreatic cancer include gemzar based regimen or FOLFIRINOX (5-FU, oxaliplatin, and irinotecan)\n\* Prior cetuximab, panitumumab, or other monoclonal antibody therapy allowed if given 28 days prior to the 1st infusion of armed T cells\n\* Absolute Neutrophil Count (ANC) \u2265 1,000/mm3\n\* Lymphocyte count \u2265 400/mm3\n\* Platelet Count \u2265 50,000/mm3\n\* Hemoglobin \u2265 8 g/dL\n\* Serum Creatinine \\< 2.0 mg/dl, Creatinine Clearance \u226550 ml/mm (can be calculated)\n\* Total Bilirubin \u2264 2 mg/dl (biliary stent is allowed)\n\* SGPT and SGOT \\< 5.0 times normal\n\* LVEF \u2265 45% at rest (MUGA or Echo)\n\* Pulse Oximetry of \\>88%\n\* Age \u2265 18 years at the time of consent\n\* Written informed consent and HIPAA authorization for release of personal health information\n\* Females of childbearing potential, and males, must be willing to use an effective method of contraception\n\* Females of childbearing potential must have a negative pregnancy test within 7 days of being registered for protocol therapy\n\* KPS \u2265 70% or SWOG Performance Status 0 or 1\n\nExclusion Criteria:\n\n\* Any chemotherapy related toxicities from prior treatment.(\\> grade I per CTCAE v4.0\n\* Known hypersensitivity to cetuximab or other EGFR antibody\n\* Treatment with any investigational agent within 14 days prior to being registered for protocol therapy Protocol version: 07/13/2011 8\n\* Symptomatic brain metastasis\n\* Chronic treatment with systemic steroids or another immuno-suppressive agent\n\* Serious non-healing wound, ulcer, bone fracture, major surgical procedure, open biopsy or significant traumatic injury within 28 days prior to being registered for protocol therapy\n\* Active liver disease such as cirrhosis, chronic active hepatitis or chronic persistent hepatitis\n\* HIV infection\n\* Positive HbsAg\n\* Positive Hepatitis C\n\* Active bleeding or a pathological condition that is associated with a high risk of bleeding\n\* Uncontrolled systemic disease like active infections\n\* Nonmalignant medical illnesses that are uncontrolled or a controlled illness that may be jeopardized by the treatment with protocol therapy\n\* Females must not be breastfeeding\n\* Patient may be excluded if, in the opinion of the PI and investigator team, the patient is not capable of being compliant\n\nMinor changes from these guidelines will be allowed at the discretion of the attending team under special circumstances. The reasons for exceptions will be documented.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"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 provided for the clinical trial, the presence of an EGFR gene mutation is not specifically mentioned as an inclusion or exclusion criterion. Therefore, a patient with an EGFR gene mutation may still be eligible for this clinical trial, provided they meet all other specified criteria.  
  
The main inclusion criteria focus on the type of cancer (colorectal or pancreatic), treatment history, and specific health metrics (such as blood counts and liver function). The exclusion criteria include factors such as chemotherapy-related toxicities, hypersensitivity to EGFR antibodies like cetuximab, and other health conditions or recent treatments that might interfere with the study.   
  
Unless the presence of an EGFR mutation implicates hypersensitivity to EGFR antibodies or affects treatment compliance in a way not specified in the criteria, the mutation itself would not inherently disqualify an individual from participating in this study. It's important for potential participants or their healthcare providers to discuss the specifics with the clinical trial's research team to confirm eligibility.