# 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:  
This trial does \*not\* select for patients based on EGFR gene mutations. It \*does\*, however, exclude patients with a "known hypersensitivity to cetuximab or other EGFR antibody". Cetuximab is a drug that targets the EGFR protein, so patients who have had bad reactions to it or similar drugs are excluded.  
  
Having an EGFR mutation doesn't automatically qualify or disqualify someone. The key criteria are having metastatic colorectal or pancreatic adenocarcinoma, having progressed on standard chemotherapy (or stable disease after first-line chemo), and meeting the other inclusion/exclusion criteria (like blood counts, organ function, etc.).