# Clinical Trials Data EGFR - Document 24

# A Study of ABT-414 in Subjects With Solid Tumors

## Clinical Trial: https://clinicaltrials.gov/study/NCT01741727

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Subjects must have a solid tumor type likely to over-express Epidermal Growth Factor Receptor (EGFR) (Phase 1)\n2. Subjects have an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0-2\n3. Subjects have available tumor tissue\n4. Subjects have adequate bone marrow, renal, and hepatic function as follows: Bone marrow: Absolute neutrophil count (ANC) \\>/= 1,500/mm3 Platelets \\>/= 100,000/mm3; Hemoglobin \\>/= 9.0 g/dL Renal function: Serum creatinine \\</= 1.5 times the upper limit of the institution's normal range Hepatic function: Bilirubin, aspartate aminotransferase (AST), and alanine aminotransferase (ALT) \\</= 1.5 times the upper limit of the institution's normal range. Subjects with liver metastasis may have an AST and ALT of \\</= 5.0 x the upper limit of normal.\n5. Subjects in the Phase 2 portion must have squamous cell Non-Small Cell Lung Cancer (NSCLC)\n6. Eligibility is restricted to subjects with confirmed EGFR amplification in the EGFR amplified cohort\n\nExclusion Criteria:\n\n1. The subject has uncontrolled metastases to the central nervous system (CNS). Subjects with brain metastases are eligible provided they have shown clinical and radiographic stable disease for at least 28 days after definitive therapy and have not received prior whole brain radiation (Phase 1 only).\n2. The subject has received anticancer therapy including chemotherapy, immunotherapy, radiotherapy, hormonal, biologic, or any investigational therapy within a period of 28 days prior to the first dose of ABT-414.\n3. The subject has unresolved clinically significant toxicities from prior anticancer therapy, defined as any Common Terminology Criteria for Adverse Events (CTCAE) Grade 2 or higher.\n4. The subject had had major surgery within 28 days prior to the first dose of ABT-414.\n5. The subject has a history of immunologic reaction to any Immunoglobulin G (IgG) containing agent.\n6. Phase 2 portion only: The subject has previous or concurrent cancer that is distinct in primary site or histology from NSCLC, except cervical carcinoma in situ, non-melanoma carcinoma of the skin or in situ carcinoma of the bladder. Any cancer curatively treated greater than 3 years prior to entry is permitted.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
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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:  
A patient with an EGFR gene mutation \*might\* be eligible, but more information is needed. Here's why:  
  
\* \*\*Inclusion Criteria 1 (Phase 1):\*\* Requires a solid tumor likely to \*over-express\* EGFR. A mutation in EGFR doesn't automatically mean overexpression. These are related but distinct concepts. A tumor could have a mutation but not overexpress the protein, or it could overexpress the protein without a specific activating mutation.  
\* \*\*Inclusion Criteria 6 (Phase 2):\*\* Requires \*confirmed EGFR amplification\* for the EGFR amplified cohort. This is different from just having an EGFR mutation. Amplification means there are multiple copies of the EGFR gene, leading to increased production. Some EGFR mutations can lead to amplification, but not all. Also note this criteria only applies to Phase 2.  
  
\*\*Therefore:\*\*  
  
\* \*\*For Phase 1:\*\* The patient \*might\* be eligible if their tumor overexpresses EGFR, even if it's due to a mutation. More information about the tumor's EGFR expression is needed.  
\* \*\*For Phase 2:\*\* The patient is only eligible if they have squamous cell NSCLC \*and\* confirmed EGFR amplification. Just having an EGFR mutation is insufficient for eligibility in Phase 2.  
  
The patient needs to be evaluated to determine if their specific EGFR mutation leads to overexpression (for Phase 1 consideration) or amplification (for Phase 2 consideration). They also need to meet all other inclusion and exclusion criteria.