# 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.",  
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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:  
Based on the provided clinical trial eligibility criteria, a patient with an EGFR gene mutation may potentially be eligible, but it would depend on other factors as well. The key considerations regarding eligibility for such a patient are:  
  
1. \*\*Inclusion Criteria\*\*:  
 - The patient’s tumor type must be likely to over-express EGFR. If the EGFR mutation results in overexpression, this may apply.  
 - For the Phase 2 portion, the patient must have squamous cell non-small cell lung cancer (NSCLC). The patient must also have a confirmed EGFR amplification in the EGFR amplified cohort. It's important to differentiate between EGFR mutation and amplification, as they are distinct genetic changes.  
   
2. \*\*Additional Requirements\*\*:  
 - The patient must have an ECOG Performance Status of 0-2, available tumor tissue, and adequate bone marrow, renal, and hepatic function.  
 - For those with liver metastasis, the AST and ALT levels must be ≤ 5.0 times the upper limit of normal.  
  
3. \*\*Exclusion Criteria\*\*:  
 - The patient should not have uncontrolled CNS metastases unless criteria for stability and therapy are met.  
 - There should be no recent anticancer therapies or unresolved clinically significant toxicities.  
  
In conclusion, if the patient with an EGFR mutation has a confirmed EGFR amplification (as required for the Phase 2 portion of the trial) and meets all other inclusion and exclusion criteria, they may be eligible. It's important to verify the mutation status (amplification vs. mutation) and discuss with the clinical trial team for clarification.