# Clinical Trials Data EGFR - Document 10

# Dynamic Circulating Tumor Cell (CTC) Changes During the Chemotherapy in NSCLC

## Clinical Trial: https://clinicaltrials.gov/study/NCT01740804

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Patients with histologically documented, locally advanced or recurrent (stage IIIb and not amenable or combined modality treatment) or metastatic (stage IV) non-small cell lung cancer.\n\* ECOG performance status of \u2264 2.\n\* Patients without prior chemotherapy or therapy with systemic anti-neoplastic therapy. Previous adjuvant or neo-adjuvant treatment or combine chemoradiotherapy for stage I to III is permitted if completed \\> 12 months before enrollment.\n\* According to routine first line doublet chemotherapy in clinical practice, Cisplatin or carboplatin combined with gemcitabine or paclitaxel or docetaxol or Vinorelbine were recommended.\n\* Patients must have measurable disease according to the RECIST (version 1.1) criteria.\n\* Life expectancy of at least 12 weeks.\n\* Age \u2265 18 years.\n\* Written (signed) informed Consent to participate in the study.\n\* Adequate organ function as defined by the following criteria:Liver function: SGOT (AST) and SGPT (ALT) \u2264 2.5 X ULN in the absence of liver metastases or up to 5 X ULN in case of liver metastases. Total bilirubin \u2264 1.5ULN.Bone marrow function: Granulocyte count \u2265 1,500/mm3 and platelet count \u2265100,000/mm3 and hemoglobin \u226590g/dl. Renal function: serum creatinine \u2264 1.5 ULN or creatinine clearance \u2265 60 ml/min. (based on modified Cockcroft-Gault formula).\n\* For all females of childbearing potential a negative serum/urine pregnancy test must be obtained within 48 hours before enrollment. Postmenopausal women must have been amenorrhoeic for at least 12 months to be considered of non-childbearing potential.\n\nExclusion Criteria:\n\n\* Patients with prior chemotherapy or therapy with systemic anti-cancer therapy including target therapy. Previous adjuvant or neo-adjuvant treatment for non-metastatic disease is permitted if completed \u2265 6 months before the enrollments.\n\* Patients with history of any other malignancies within 5 years (except for adequately treated carcinoma in situ of the cervix or basal or squamous cell skin cancer).\n\* Patients who have brain metastasis or spinal cord compression. It is permitted if the patient has been treated with surgery and/or radiation with evidence of stable disease for at least 4 weeks.\n\* Patients who are at risk (in the investigator's opinion) of transmitting human immunodeficiency virus (HIV) through blood or other body fluids.\n\* Nursing or lactating women.\n\* Sexually active males and females (of childbearing potential) unwilling to practice contraception during the study.\n\* Unwilling to write informed consent to participate in the study.\n\* Patients who is unwilling to accept the follow-up.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
],  
 "studyPopulation": "Advanced NSCLC (stage IIIb/IV or recurrent NSCLC)",

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, there is no specific mention of exclusion or inclusion criteria related to patients with EGFR gene mutations. The primary focus seems to be on the stage of non-small cell lung cancer (NSCLC), performance status, chemotherapy history, and general health conditions.  
  
Since the criteria specify that patients can have stage IIIb/IV or recurrent NSCLC and do not explicitly exclude those with genetic mutations such as EGFR, a patient with an EGFR mutation may still be eligible, assuming all other requirements are met. It is important to confirm with the specific clinical trial coordinators or investigators for any additional eligibility considerations specific to genetic mutations or targeted therapies.