# Clinical Trials Data KRAS - Document 29

# 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 KRAS gene mutation be eligible for the clinical trial?

Answer:  
This clinical trial information \*\*does not mention KRAS mutation status\*\* as either an inclusion or exclusion criterion. Therefore, having a KRAS mutation would \*not automatically disqualify\* a patient from participating. They would need to meet all other inclusion criteria and not meet any of the exclusion criteria to be eligible.