# Clinical Trials Data EGFR - Document 90

# ATOM\_local Ablative Therapy

## Clinical Trial: https://clinicaltrials.gov/study/NCT01941654

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Pathologically confirmed UICC 7th edition Stage IIIB (not amenable for curative intent local radiotherapy)/IV (metastatic or recurrent) non-small cell carcinoma of lung\n2. Documented activating EGFR mutation (exon 19 deletion or exon 21 L858R only) in tumor tissues\n3. Treated with first-line EGFR TKI for 3 months and achieved good radiological partial response that was documented with a CT scan\n4. Not more than 4 residual metabolic active (SUVmax \\> 2.5) metastatic sites left on the screening PET-CT scan. (one bone metastatic site is regarded as a single site, mediastinal/ hilar lymph nodes in close proximity and possible to be treated in an acceptable volume is regarded as one lesion)\n5. The shortest diameter of the lesion must be \u2265 1cm and is amenable to local ablative therapy\n6. Eastern Cooperative Oncology Group (ECOG) performance status 0 - 2\n7. Age \u2265 18 years\n8. Pleural or pericardial effusion at diagnosis is allowed only if it has resolved on CT scan after 3-month EGFR TKI treatment\n9. Brain metastasis at diagnosis is allowed if it has been treated either surgically or with radiotherapy and there is no radiological progression on follow-up CT scan. The patient is neurologically stable for at least 1 week after cessation of steroid treatment\n10. Adequate organ function as defined by the following criteria:\n\n 1. Serum alanine transaminase \u2264 3 x upper limit of normal (ULN) or \u2264 5 x ULN if liver function abnormalities are due to liver metastases\n 2. Total bilirubin \u2264 1.5 x ULN\n 3. Absolute neutrophil count (ANC) \u2265 1.5 x 109/L\n 4. Platelets count \u2265 100 x 109/L\n 5. Creatinine clearance \\> 45ml/min\n11. Written informed consent that is consistent with ICH-GCP guidelines\n\nExclusion Criteria:\n\n1. Prior chemotherapy is not allowed except adjuvant chemotherapy for completely resected early staged non-small cell lung cancer and it has been at least 12 months before the start of EGFR TKI treatment\n2. Prior radiotherapy is not allowed except brain irradiation\n3. Leptomeningeal carcinomatosis\n4. Lymphangitis carcinomatosis of lung\n5. Prior or concomitant malignancy at other sites is not allowed except treated non-metastatic non-melanoma skin cancer, ductal carcinoma-in-situ of breast and carcinoma-in-situ of cervix with curative intent\n6. Uncontrolled active infection or medical condition (e.g. uncontrolled hypertension, unstable angina, congestive heart failure \\[\u2265 NYHA Class II\\], uncontrolled arrhythmia, myocardial infarction or cerebrovascular accident within the past 6 month)\n7. Pre-existing interstitial lung disease\n8. Woman of child-bearing potential or male patient is unwilling to use adequate birth control method prior to the study entry, for the duration of study participation and for at least 2 months after the EGFR TKI treatment has ended.\n9. Pregnant and Lactating female patient\n10. Non-compliance to the study procedure",  
 "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:  
A patient with an EGFR gene mutation \*might\* be eligible for this trial. Simply having the mutation is not enough. They must meet \*all\* of the inclusion criteria and \*none\* of the exclusion criteria. Specifically regarding the EGFR mutation, it must be an \*\*activating EGFR mutation (exon 19 deletion or exon 21 L858R only).\*\* Other EGFR mutations would exclude the patient. Furthermore, the patient must meet all other criteria outlined in the inclusion and exclusion sections.