# Clinical Trials Data EGFR - Document 27

# Study of Nivolumab (BMS-936558) in Combination With Gemcitabine/Cisplatin, Pemetrexed/Cisplatin, Carboplatin/Paclitaxel, Bevacizumab Maintenance, Erlotinib, Ipilimumab or as Monotherapy in Subjects With Stage IIIB/IV Non-small Cell Lung Cancer (NSCLC) (CheckMate 012)

## Clinical Trial: https://clinicaltrials.gov/study/NCT01454102

"eligibilityCriteria": "For more information regarding BMS clinical trial participation, please visit www.BMSStudyConnect.com\n\nInclusion Criteria:\n\n\* Newly diagnosed and confirmed Stage IIIB/IV NSCLC\n\* Previously treated NSCLC with asymptomatic brain metastases (eligible for Arm M) See additional details below\n\* Men and women aged \u226518 years\n\* Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1\n\* Subject must be chemotherapy naive (except Arm D, K, L and M). Prior use of epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) is acceptable. For Arms D, K, and L, subjects must be non-progressors within 42 days after completion of first-line treatment with \u22654 cycles of Platinum Doublet chemotherapy with or without Bevacizumab. See below for Arm M\n\* Either a formalin fixed tissue block or a minimum of 10 slides of tumor sample (archived or fresh) must be available for biomarker evaluation (a local pathologist must review for adequacy of sampling)\n\* Life expectancy of at least 3 months\n\* Prior radiotherapy must have been completed at least 2 weeks prior to study entry\n\nFor Arm M:\n\n\* No more than 4 brain metastases\n\* Each brain metastases \u22643 cm in size\n\* No evidence of cerebral edema\n\* Subjects must be free of neurologic symptoms related to metastatic brain lesions and must not have required or received systemic corticosteroids for \u226510 days prior to initiation of study treatment\n\* At least 1 measurable target brain lesion \\>0.5 cm and no larger than 3 cm in diameter and/or 2 measurable brain target lesions \\>0.3 cm\n\* No prior radiation therapy, surgery, or other local therapy for target brain lesions\n\* Must have received at least one prior systemic anticancer therapy for NSCLC\n\nExclusion Criteria:\n\n\* Subjects with symptomatic brain metastases, spinal cord compression, or intractable back pain due to a compressive or destructive mass\n\* Subjects who require emergent use of systemic steroids, emergent surgery and/or radiotherapy\n\* Any active or history of a known autoimmune disease\n\* Subjects with previous malignancies (except non-melanoma skin cancers, in situ bladder cancer, gastric, or colon cancers or cervical cancers/dysplasia, or breast carcinoma in situ) are excluded unless a complete remission was achieved at least 2 years prior to study entry and no additional therapy is required or anticipated to be required during the study period\n\* History of Grade \u22652 neuropathy\n\* Subjects with interstitial lung disease that is symptomatic or may interfere with the detection or management of suspected drug-related pulmonary toxicity",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
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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 would generally be eligible for this clinical trial as the eligibility criteria specifically allow for the prior use of epidermal growth factor receptor (EGFR) tyrosine kinase inhibitors (TKIs). Here are some key points:  
  
1. The trial includes patients with Stage IIIB/IV NSCLC, which would cover those with EGFR mutations that are often relevant in adenocarcinoma cases.  
2. Prior use of EGFR TKI is acceptable, suggesting that patients with EGFR mutations, who are typically treated with TKIs, are eligible.  
3. The criteria do not explicitly exclude patients with an EGFR gene mutation. Rather, they accommodate prior TKI treatment, which is specific to EGFR-mutant NSCLC.  
  
Therefore, on the basis of the given eligibility criteria, a patient with an EGFR gene mutation would not be excluded and would be eligible for this clinical trial. However, all other inclusion and exclusion criteria must also be met to confirm eligibility.