# Clinical Trials Data BRAF - Document 53

# Combined BRAF-Targeted Therapy & Immunotherapy for Melanoma

## Clinical Trial: https://clinicaltrials.gov/study/NCT01754376

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Histologically confirmed metastatic or unresectable melanoma with V600E mutation\n\* Measurable disease\n\* May have received prior immunotherapy (excluding interleukin 2)\n\* Life expectancy greater than 3 months\n\* Recovered from effects of previous surgery and/or traumatic injury\n\* Must agree to use effective contraception\n\nExclusion Criteria:\n\n\* Pregnant or breastfeeding\n\* Psychological, familial or other conditions that could hamper compliance with protocol\n\* Receiving other study agents\n\* History of carcinomatous meningitis\n\* Known active brain metastases\n\* Have received a BRAF inhibitor\n\* Uncontrolled intercurrent illness\n\* HIV positive on antiretroviral therapy\n\* History of a different malignancy within past 5 years (except cervical cancer in situ or basal/squamous cell carcinoma of the skin)\n\* Active hepatitis B or C\n\* Have received allogenic bone marrow transplant or organ transplant",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

Question:  
Based on the following clinical trial information, would a patient with a BRAF gene mutation be eligible for the clinical trial?

Answer:  
Based on the provided inclusion and exclusion criteria, a patient with a BRAF V600E mutation would be eligible for this clinical trial, as the inclusion criteria specify that participants must have metastatic or unresectable melanoma with this specific mutation.  
  
However, the eligibility of the patient also depends on other factors. They must not have received a BRAF inhibitor, as listed in the exclusion criteria. Additionally, they must meet other criteria such as having a life expectancy greater than 3 months, having recovered from previous treatments, agreeing to use contraception, and not having other disqualifying conditions listed in the exclusion criteria.  
  
Therefore, while the presence of a BRAF V600E mutation is necessary for eligibility, the patient must be assessed against all other criteria to determine full eligibility for the trial.