# 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:  
No. The exclusion criteria specifically lists "Have received a BRAF inhibitor" and "History of a different malignancy within past 5 years". While the patient has a BRAF mutation (which is often the target of BRAF inhibitors), this trial is looking at other treatments in patients who \*haven't\* had a BRAF inhibitor before.