# Clinical Trials Data BRAF - Document 28

# Radiation Use During Vemurafenib Treatment

## Clinical Trial: https://clinicaltrials.gov/study/NCT02042040

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Age \\> 18 years old\n\* Diagnosis of BRAFV600 mutated Stage IV or unresectable Stage III melanoma\n\* Actively receiving treatment with vemurafenib as single agent and tolerating at least 720 mg bid for one cycle (28 days).\n\* In the opinion of the investigator, patients who are progressing in an area where radiation may provide benefit from either:\n\n \* Symptom control\n \* Oligo-progression, defined as progression in up to 3 areas where focal treatment would provide benefit.\n\* Patients with brain metastases will be allowed provided they meet all of the following criteria:\n\n \* Small, \\< 1cm metastases which are untreated are allowed so long as in the opinion of the investigator they do not require immediate treatment by radiation or surgery\n \* Asymptomatic, treated brain metastases which are stable for 4 weeks prior to study entry are allowed\n \* If patients are requiring steroids for their brain metastases, they must be on a stable dose for two weeks prior to study entry, and maintain that steroid dosing during the radiation treatments\n\* Adequate bone marrow function as defined by: ANC \\> 1.0 k/uL, Platelets \\> 75 k/uL, Hemoglobin \\> 8 g/dL\n\* Adequate hepatic function: Total bilirubin \\< 1.5 times the institutional upper limit of normal, ALT/AST \\< 2.5 times the institutional upper limit of normal\n\* Adequate renal function as defined by serum creatinin \\< 1.5 times the upper limit of normal.\n\* Negative serum pregnancy test at screening for women of child bearing potential within 10 days of starting vemurafenib treatment . Women of non-childbearing potential may be included if they are either surgically sterile or have been postmenopausal for \\> 1 year\n\* Fertile men and women must agree to use an acceptable method of birth control during treatment and for at least 2 months after discontinuation of vemurafenib.\n\* Able and willing to provide informed consent to an approved consent form that conforms to federal and institutional guidelines.\n\nExclusion Criteria:\n\n\* Screening QTc interval \\> 450 msec on EKG\n\* Known HIV positivity or AIDS-related illness, or active HBV, or active HCV.\n\* Any of the following within the 6 months prior to study drug administration: myocardial infarction, severe/unstable angina, coronary/peripheral artery bypass graft, symptomatic congestive heart failure, serious cardiac arrhythmia requiring medication, uncontrolled hypertension, cerebrovascular accident or transient ischemic attack, or symptomatic pulmonary embolism.\n\* Malabsorption disorder that would preclude adequate vemurafenib absorption.\n\* Other medical condition present that in the opinion of the investigator will hinder the subjects ability to complete the study.",  
 "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 information provided from the clinical trial eligibility criteria, a patient with a BRAF gene mutation, specifically a BRAFV600 mutation, would be eligible for the clinical trial if they meet the other inclusion criteria and do not meet any of the exclusion criteria.   
  
Key points from the inclusion criteria relevant to patients with a BRAF mutation are:  
  
- The diagnosis should be BRAFV600 mutated Stage IV or unresectable Stage III melanoma.  
- The patient should already be actively receiving treatment with vemurafenib as a single agent and tolerating a dose of at least 720 mg twice daily for one cycle (28 days).  
  
The presence of a BRAFV600 mutation fits one of the main inclusion criteria for the study. As long as the patient meets the other criteria and does not fall under any exclusion criteria, they would be eligible to participate in the clinical trial.