# Clinical Trials Data BRAF - Document 36

# Circulating Melanoma Cells in Metastatic Patients Treated With Selective BRAF Inhibitors

## Clinical Trial: https://clinicaltrials.gov/study/NCT01878396

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Fourth stage Melanoma patients with both measurable and not measurable lesions undergoing treatment with selective B-RAF inhibitors will be included. To determine the prevalence of CMC-positive patients in IV stage Melanoma, patients without mutated B-RAF undergoing chemotherapy and/or vaccines will be also enrolled at baseline, as part of study protocols approved and activated in the participating centers.\n\* Informed written consent.\n\nExclusion Criteria:\n\n\* Inadequate compliance to multiple blood draws (baseline, 15 days, 1th month, 4th month, and/or at progression) as scheduled in this adjunctive biologic study for patients carrying B-FAF mutation; inadequate compliance to adjunctive blood draws, as scheduled at baseline for BRAF wild-type\n\* Previously exposure to immunological treatment.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
],  
 "studyPopulation": "Primary care clinic",

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

Answer:  
Yes, a patient with a stage IV melanoma and a BRAF mutation would likely be eligible for this trial. The inclusion criteria specifically state, "\* Fourth stage Melanoma patients with both measurable and not measurable lesions undergoing treatment with selective B-RAF inhibitors will be included." Having the BRAF mutation and being treated with a B-RAF inhibitor is a key inclusion criterion.  
  
However, it's crucial to note the following:  
  
\* \*\*Other factors matter:\*\* The patient must also meet \*all other\* inclusion criteria (e.g., informed consent) and \*not\* meet any exclusion criteria (e.g., prior immunotherapy). The frequency of blood draws could be a challenge for some patients.  
\* \*\*"Also enrolled" group:\*\* The trial \*also\* enrolls stage IV melanoma patients \*without\* BRAF mutations who are receiving chemotherapy and/or vaccines. This doesn't exclude patients \*with\* the mutation, but highlights a secondary group being studied.  
\* \*\*"Adjunctive" study:\*\* This is described as an "adjunctive biologic study," meaning it likely runs alongside the patient's primary B-RAF inhibitor treatment. This isn't a trial \*of\* a B-RAF inhibitor, but rather a study happening \*in addition to\* it.  
  
  
The patient should discuss the trial thoroughly with their oncologist to ensure they fully understand the implications and requirements.