# Clinical Trials Data BRAF - Document 16

# Clinical Evaluation of the Underlying Mechanisms of Targeted Therapy Related Toxicities

## Clinical Trial: https://clinicaltrials.gov/study/NCT01758575

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Patients that will start palliative treatment with TKIs, mTOR inhibitors, ipilimumab, vemurafenib or EGFR inhibitors and therefore fulfill according to their attending physician all the usual criteria for receiving standard targeted therapy as monotherapy.\n2. PT-INR/PTT \\< 1.5 x ULN.\n3. Platelet count \\>/= 100 x 109/l\n\nExclusion Criteria:\n\n1. Concomitant use of anticoagulants\n2. Previous colonic surgery in the last 3 months\n3. History of inflammatory bowel disease, or other active gastrointestinal infection",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
],  
 "studyPopulation": "Patients with advanced or metastatic solid malignancy, amenable to standard treatment with targeted agents will be included from the VUmc Medical Oncology outpatient clinic.",

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

Answer:  
Potentially yes. The patient \*might\* be eligible. Here's why:  
  
\* \*\*Inclusion Criteria 1 is key:\*\* The trial includes patients starting palliative treatment with "vemurafenib." Vemurafenib is a BRAF inhibitor specifically used for patients \*with\* BRAF mutations (like melanoma). So, having the BRAF mutation is necessary for treatment with vemurafenib, and therefore, allows the patient to potentially meet this inclusion criterion.  
\* \*\*The other criteria need to be met:\*\* The patient also needs to meet the other inclusion criteria (INR/PTT and platelet counts) and \*not\* have any of the exclusion criteria (anticoagulants, recent surgery, GI issues).  
  
\*\*In short:\*\* The BRAF mutation itself doesn't exclude the patient, and is actually required for one of the listed treatments. However, full eligibility depends on meeting \*all\* inclusion criteria and \*none\* of the exclusion criteria. More information about the patient's specific condition and treatment plan would be needed to determine definitive eligibility.