# Clinical Trials Data BRAF - Document 11

# Midostaurin (PKC412) for Locally Advanced Rectal Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01282502

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Adenocarcinoma of the rectum\n\* T3/4 or N+ disease\n\* Life expectancy \\> 3 months\n\* Normal organ and marrow function\n\nExclusion Criteria:\n\n\* Metastatic disease\n\* Pregnant or breastfeeding\n\* Prior radiotherapy\n\* Receiving other investigational agents\n\* History of inflammatory bowel disease\n\* Active scleroderma or CREST syndrome\n\* Uncontrolled intercurrent illness\n\* History of a different malignancy unless disease free for at least 5 years\n\* HIV or active viral hepatitis\n\* Impaired cardiac function",  
 "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 eligibility criteria for the clinical trial, there is no specific mention of exclusion based on a BRAF gene mutation. The trial includes patients with adenocarcinoma of the rectum with T3/4 or N+ disease and other specified criteria about their health and past medical treatments. As long as the patient meets these criteria and does not fall under any of the listed exclusion criteria (such as metastatic disease or concurrent illness), the presence of a BRAF gene mutation alone does not make the patient ineligible for this trial.  
  
However, the trial organizers might need to confirm understanding, as additional considerations not listed could potentially affect eligibility, such as the molecular signature or specific response expected in this trial. If there's any concern or need for confirmation due to nuanced details not included in this information, it may be best to contact the trial organizers directly.