# Clinical Trials Data BRAF - Document 39

# Dabrafenib With Trametinib in the Adjuvant Treatment of High-risk BRAF V600 Mutation-positive Melanoma (COMBI-AD).

## Clinical Trial: https://clinicaltrials.gov/study/NCT01682083

"eligibilityCriteria": "Key Inclusion Criteria:\n\n\* Completely resected histologically confirmed high-risk \\[Stage IIIa (LN metastasis more than 1 mm), IIIb or IIIc cutaneous melanoma determined to be V600E/K mutation positive by a central laboratory. Patients presenting with initial resectable lymph node recurrence after a diagnosis of Stage I or II melanoma are eligible.\n\* Surgically rendered free of disease no more than 12 weeks before randomization.\n\* Recovered from definitive surgery (e.g. no uncontrolled wound infections or indwelling drains).\n\* Eastern Cooperative Oncology Group (ECOG) Performance Status of 0-1.\n\* Adequate hematologic, hepatic, renal and cardiac function.\n\nKey Exclusion Criteria:\n\n\* Known mucosal or ocular melanoma or the presence of unresectable in-transit metastases.\n\* Evidence of distant metastatic disease.\n\* Prior systemic anti-cancer treatment and radiotherapy for melanoma; prior surgery for melanoma is allowed.\n\* History of another malignancy or concurrent malignancy including prior malignant melanoma. Exceptions to this include: Patients who have been disease-free for 5 years or patients with a history completely resected non-melanoma skin cancer or successfully treated in situ carcinoma are eligible, for example cervical cancer in situ, atypical melanocytic hyperplasia or melanoma in situ, multiple primary melanomas, or other malignancies for which the patient has been disease free for \\> 5 years.\n\* History or current evidence of cardiovascular risk.\n\* History or current evidence of retinal vein occlusion (RVO) or central serous retinopathy (CSR)",  
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"OLDER\_ADULT"  
]  
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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 key inclusion criteria for the clinical trial, a patient with a BRAF gene mutation, specifically a V600E or V600K mutation, would be eligible for the trial. The inclusion criteria explicitly mention that patients with completely resected, histologically confirmed high-risk Stage IIIa, IIIb, or IIIc cutaneous melanoma that is determined to be V600E/K mutation positive are eligible.  
  
If the patient's BRAF mutation is of the V600E or V600K type, they meet this particular criterion for inclusion, provided they also meet the other inclusion criteria, such as being surgically rendered free of disease, having recovered from surgery, having an ECOG Performance Status of 0-1, and having adequate organ function. Additionally, they must not meet any of the exclusion criteria to be considered eligible.