# 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:  
A patient with \*only\* a BRAF gene mutation is \*\*not necessarily eligible\*\* for this trial. The inclusion criteria specify that the melanoma must be \*\*V600E/K mutation positive\*\*. While V600E and V600K are specific types of BRAF mutations, other BRAF mutations exist. If the patient's BRAF mutation is \*not\* V600E or V600K, they would be excluded. Only a patient with a confirmed V600E or V600K BRAF mutation would meet this specific requirement.