# Clinical Trials Data KIT - Document 50

# Sunitinib® in Patients With Recurrent Ovarian Clear Cell Carcinoma

## Clinical Trial: https://clinicaltrials.gov/study/NCT01824615

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Histologically (Primary tumor with \u2265 50% clear cell histomorphology) or cytologically confirmed ovarian clear cell carcinoma The disease should be documented recurrence or resistant to primary platinum and paclitaxel based adjuvant chemotherapy.\n\n \* Patients are relapsed, not amenable to curative surgery or radiotherapy.\n \* not considered to required palliative chemotherapy nor radiotherapy\n \* Abnormal elevated serum CA125 tumor marker for no measurable disease by physical examination or image study, roentgenogram or computed tomography (CT) scan. Serum level of CA125 is higher than 80 IU/ml, or serum level of CA125 is at least 2 fold on day 14 than original serum level of CA125 which is higher than 35 IU/ml but less than 80 IU/ml on day 0.\n2. Evidence of measurable disease according to the Response Evaluation Criteria in Solid Tumors (RECIST) guidelines.\n3. Female, 20 years of age or older.\n4. GOG performance status of 0 - 2.\n\n \* GOG performance status 0-2\n \* Resolution of all acute toxic effects of prior chemotherapy, radiotherapy, or surgery to NCI CTCAE grade \u22641(except for alopecia).\n \* Life expectancy of at least 8 weeks\n5. Adequate organ function as defined by the following criteria:\n\n \* Serum aspartate transaminase (AST) and serum alanine transaminase (ALT) \u22642.5 x upper limit of normal (ULN) or AST and ALT \u22645 x ULN if liver function abnormalities are due to underlying malignancy (liver metastases)\n \* Total serum bilirubin \u22641.5 x ULN\n \* Absolute neutrophil count (ANC) \u22651500/\u00b5L\n \* Platelets \u2265100,000/\u00b5L\n \* Hemoglobin \u22659.0 g/dL\n \* Serum creatinine \u22641.5 x ULN\n \* QTc interval \u2264450 msec for males and \u2264470 msec for females (based on a mean value from 3 ECGs)\n \* Left ventricular ejection fraction (LVEF) \u2265lower limit of institutional normal (LLN) as assessed by multigated acquisition (MUGA) scan or echocardiogram\n6. Signed and dated informed consent document indicating that the patient (or legally acceptable representative) has been informed of all pertinent aspects of the trial prior to enrollment.\n7. Willingness and ability to comply with scheduled visits, treatment plans, laboratory tests, and other study procedures.\n\nExclusion Criteria:\n\n1. Any of the following: known, severe hypersensitivity to sunitinib or any of the excipient of this product, unable to swallow sunitinib, previous treatment with sunitinib\n2. Major surgery or radiation therapy within 4 weeks of study treatment.\n3. Evidence of tumor bleeding within 4 weeks of study treatment.\n4. NCI CTCAE grade \u22653 hemorrhage within 4 weeks of study treatment.\n5. Newly diagnosed CNS metastases that have not been adequately controlled\n6. Ongoing cardiac dysrhythmias of grade \u22652.\n7. Hypertension that cannot be controlled by medication (\\>150/100 mmHg despite optimal medical therapy).\n8. Any of the following within the 12 months prior to study treatment: myocardial infarction, severe/unstable angina, coronary/peripheral artery bypass graft, congestive heart failure, cerebrovascular accident including transient ischemic attack, or pulmonary embolism.\n9. Diagnosis of any second malignancy within the last 3 years, except basal cell carcinoma, squamous cell skin cancer, or in situ carcinoma that has been adequately treated with no evidence of recurrent disease for 12 months.\n10. Ongoing treatment with therapeutic doses (with therapeutic INR levels) of coumarin derivatives (low dose up to 2 mg PO daily for deep vein thrombosis prophylaxis is allowed) or oral anti-vitamin K agents.\n11. PT \\>1.5 x ULN\n12. Known human immunodeficiency virus (HIV) infection.\n13. Current treatment on another clinical trial.\n14. Pregnancy or breastfeeding. Patients who are unwilling or unable to use adequate contraception to prevent pregnancy during the study. All female patients with reproductive potential must have a negative pregnancy test prior to study entry.",  
 "healthyVolunteers": false,  
 "sex": "FEMALE",  
 "minimumAge": "20 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

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

Answer:  
Based on the provided clinical trial information, there is no specific mention of a KIT gene mutation either in the inclusion or exclusion criteria. Therefore, having a KIT gene mutation in itself does not appear to directly affect eligibility for the trial.  
  
Key Inclusion Criteria:  
- Histologically or cytologically confirmed ovarian clear cell carcinoma that is recurrent or resistant to primary platinum and paclitaxel based adjuvant chemotherapy.  
- Evidence of measurable disease according to RECIST guidelines.  
- Female patients, 20 years or older, with a GOG performance status of 0-2, and adequate organ function.  
  
Key Exclusion Criteria:  
- Severe hypersensitivity to sunitinib or previous treatment with it.  
- Recent surgery or radiation therapy, among others.  
  
Since a KIT gene mutation isn't listed as a criterion, a patient with such a mutation could be eligible as long as they meet all the inclusion criteria and none of the exclusion criteria. It would still be prudent for the patient to discuss specific eligibility with the clinical trial team, as there could be additional considerations not listed in the provided excerpt.