# Clinical Trials Data EGFR - Document 97

# Dacomitinib (PF-00299804) in Advanced/Metastatic Squamous Cell Carcinoma of the Penis

## Clinical Trial: https://clinicaltrials.gov/study/NCT01728233

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Patients must provide written informed consent\n\* Eastern Cooperative Oncology Group performance status of at least 1\n\* Cytologically or histologically proven diagnosis of SCC of the penis\n\* Uni- or bidimensionally measurable disease as defined by RECIST v1.1 criteria\n\* Clinical stage N2-3 and/or M1 (TNM 2002)\n\* Locoregional relapse after prior major surgery/ies (either single or multiple)\n\* No prior systemic therapy except for the administration of vincristine-bleomycin-methotrexate (VBM) chemotherapy for superficial disease if administered at least 6 months prior to study enrollment\n\* Adequate bone marrow, liver and renal function\n\nExclusion Criteria:\n\n\* Central nervous system (CNS) metastases or leptomeningeal carcinomatosis\n\* History of active serious cardiovascular, cerebrovascular, pulmonary co-morbidities\n\* Previous or concurrent cancer that is distinct in primary site or histology from the cancer being evaluated in this study EXCEPT cervical carcinoma in situ, treated basal cell carcinoma or any cancer curatively treated \\> 5 years prior to study entry.",  
 "healthyVolunteers": false,  
 "sex": "MALE",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

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

Answer:  
No. The inclusion criteria specifically state the patient must have "Cytologically or histologically proven diagnosis of SCC of the penis". EGFR mutations are associated with several cancers, but having an EGFR mutation does \*not\* qualify someone for this trial unless they also have penile squamous cell carcinoma (SCC).