# Clinical Trials Data EGFR - Document 93

# Study Of Dacomitinib (PF-00299804) In Advanced NSCLC Patients (Post Chemo Or Select First Line) To Evaluate Prophylactic Intervention On Derm And GI AEs And PRO

## Clinical Trial: https://clinicaltrials.gov/study/NCT01465802

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Advanced Non-Small Cell Lung Cancer (NSCLC).\n\* For Cohort I and Cohort II, advanced NSCLC patients must have received at least one prior regimen of systemic therapy which includes at least one standard chemotherapy for advanced NSCLC and who have failed (ie, progressed or intolerant due to toxicity which precludes further treatment) standard therapy for advanced or metastatic disease. To be considered intolerant to treatment, a patient must have received at least two cycles to be considered previously treated.\n\* For Cohort III, advanced NSCLC patients must not have received prior systemic treatment for their advanced disease and require a known EGFR (HER-1) mutation, HER-2 mutation or HER-2 amplification. Cohort III patients could have received prior adjuvant chemotherapy for Stage I-III disease or combined modality chemotherapy-radiation for Stage IIIA disease is allowed if treatment completed\\>12 months prior to enrollment.\n\* All cohorts, patients must have evidence of disease; however, measurable disease is not required to enroll.\n\* Eastern Cooperative Oncology Group (ECOG) Performance status 0-2\n\* Estimated creatinine clearance \u226515 mL/min.\n\nExclusion Criteria:\n\n\* Prior treatment with an EGFR-targeted or HER-targeted agent (all cohorts).\n\* Chemotherapy, radiotherapy, biological or investigational agents within 2 weeks of baseline disease assessments (all cohorts).\n\* Patients with known diffuse interstitial lung disease (all cohorts).\n\* Investigational therapy as only treatment for advanced NSCLC without administration of an approved chemotherapy for advanced NSCLC (for Cohort I and Cohort II)",  
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]

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

Answer:  
A patient with an EGFR mutation \*could\* be eligible for this trial, specifically for \*\*Cohort III\*\*. Cohort III explicitly requires a known EGFR mutation (or HER-2 mutation/amplification) and allows patients who haven't received prior systemic treatment for advanced NSCLC.  
  
However, they would be excluded if they meet \*any\* of the exclusion criteria, most notably:  
  
\* \*\*Prior treatment with an EGFR-targeted or HER-targeted agent:\*\* This would disqualify them regardless of cohort.  
\* \*\*Recent treatment:\*\* Chemotherapy, radiotherapy, biological, or investigational agents within 2 weeks of baseline assessments would exclude them.  
\* \*\*Diffuse interstitial lung disease:\*\* A diagnosis of this condition is an exclusion criterion.  
  
  
It's important to note that having the EGFR mutation doesn't automatically qualify them. All other inclusion and exclusion criteria must be met.