# Clinical Trials Data ALK - Document 7

# Phase I Study of LDK378 in Pediatric, Malignancies With a Genetic Alteration in Anaplastic Lymphoma Kinase (ALK)

## Clinical Trial: https://clinicaltrials.gov/study/NCT01742286

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Diagnosed with a locally advanced or metastatic malignancy that has progressed despite standard therapy, or for which no effective standard therapy exists\n\* Age \u2265 12 months and \\< 18 years\n\* The tumor must carry a genetic alteration of ALK\n\* Patients must have evaluable or measurable disease.\n\* Karnofsky performance status score \u2265 60% for patients \\> 12 years of age; Lansky score \u2265 50% for patients \u2264 12 years of age.\n\nExclusion criteria:\n\n\* Symptomatic central nervous system (CNS) metastases who are neurologically unstable or require increasing doses of steroids or local CNS-directed therapy (such as radiotherapy, surgery or intrathecal chemotherapy) to control their CNS disease\n\* Inadequate end organ function as defined by specified laboratory values\n\* Body surface area (BSA) \\< 0.35 m2\n\* Impairment of gastrointestinal (GI) function or GI disease that may significantly alter the absorption of LDK378 (e.g., ulcerative diseases, uncontrolled nausea, vomiting, diarrhea, or malabsorption syndrome)\n\* Use of medications that are known to be strong inhibitors or inducers of CYP3A4/5 that cannot be discontinued at least 1 week prior to start of treatment with LDK378 and for the duration of the study\n\* Use of medications that are mainly metabolized by CYP3A4/5 or CYP2C9 that cannot be discontinued at least 1 week prior to start of treatment with LDK378 and for the duration of the study\n\* History of interstitial lung disease or interstitial pneumonitis, including clinically significant radiation pneumonitis\n\* History of pancreatitis or history of increased amylase or lipase that was due to pancreatic disease.\n\* Medications with a known risk of prolongation of QT interval",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "12 Months",  
"stdAges": [  
"CHILD"  
]

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

Answer:  
A patient with an ALK gene mutation \*could\* be eligible for this trial, but more information is needed. While the presence of the ALK mutation is a requirement, the patient also needs to meet \*all\* other inclusion criteria and \*none\* of the exclusion criteria.  
  
Specifically, we need to know the following about the patient:  
  
\* \*\*Age:\*\* They must be between 12 months and 18 years old.  
\* \*\*Cancer Status:\*\* They must have locally advanced or metastatic malignancy that has progressed despite standard therapy, or for which no effective standard therapy exists.  
\* \*\*Measurable Disease:\*\* Their disease must be measurable so that the treatment's effectiveness can be assessed.  
\* \*\*Performance Status:\*\* Their Karnofsky or Lansky score must meet the specified minimums (depending on age).  
\* \*\*CNS Metastases:\*\* They must \*not\* have symptomatic CNS metastases that are unstable or require increasing doses of steroids or local CNS-directed therapy.  
\* \*\*Organ Function, BSA, and GI Function:\*\* They must have adequate organ function, a BSA ≥ 0.35 m², and no significant GI impairments that would affect drug absorption.  
\* \*\*Medications:\*\* They cannot be taking certain medications that interact with CYP3A4/5 or CYP2C9, or medications that prolong the QT interval, unless those medications can be discontinued.  
\* \*\*Medical History:\*\* They cannot have a history of interstitial lung disease, radiation pneumonitis, pancreatitis, or pancreatic-related amylase/lipase increases.   
  
Only if the patient meets \*all\* these criteria would they be eligible for the trial.