# Clinical Trials Data ALK - Document 27

# Phase II Study of Decitabine and Cytarabine for Older Patients With Newly Diagnosed Acute Myeloid Leukemia (AML)

## Clinical Trial: https://clinicaltrials.gov/study/NCT01829503

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Age \u2265 70, or age \u2265 60 ineligible for treatment with standard induction chemotherapy (based on physician discretion or patient refusal), with a new diagnosis of AML based on World Health Organization Classification.\n2. Eastern Cooperative Oncology Group Performance Status of 0-2\n3. Cardiac ejection fraction \u226545%\n4. Males are eligible to enter and participate in the study if they have either had a prior vasectomy or agree to avoid sexual activity or use adequate contraception from screening through two months post the last dose of decitabine\n\nExclusion Criteria:\n\n1. Patients with acute promyelocytic leukemia\n2. Life expectancy \u22643 months\n3. Prior use of any hypomethylating agent or cytarabine\n4. Uncontrolled, life-threatening infection that is not responding to antimicrobial therapy\n5. Serum creatinine \\> 2x upper limit of normal\n6. Aspartate aminotransferase (AST),alanine aminotransferase (ALT), or total bilirubin \\> 5x upper limit of normal\n7. History of psychiatric disorder which may compromise compliance with the protocol or which does not allow for appropriate informed consent\n8. Patient may not be receiving any other antineoplastic agents (hydroxyurea is allowed)\n9. Concurrent malignancy. Exception: Subjects who have been disease-free for 5 years, or subjects with a history of completely resected non-melanoma skin cancer or successfully treated in situ carcinoma are eligible. Subjects with second malignancies that are indolent or definitively treated may be enrolled.\n10. Evidence of severe or uncontrolled systemic diseases (e.g., unstable or uncompensated respiratory, hepatic, renal, or cardiac disease).",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "60 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

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

Answer:  
The clinical trial eligibility criteria provided do not mention any specific genetic mutations, such as an ALK gene mutation, either as an inclusion or exclusion criterion. Therefore, based solely on the provided criteria, a patient with an ALK gene mutation would potentially be eligible for this clinical trial, as long as they meet all the inclusion criteria and do not meet any of the exclusion criteria.   
  
Key eligibility factors to consider include:  
  
- Age criteria: ≥70 years or ≥60 years if ineligible for standard induction chemotherapy.  
- Diagnosis of acute myeloid leukemia (AML) according to the WHO classification.  
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0-2.  
- Cardiac ejection fraction of ≥45%.  
- The absence of acute promyelocytic leukemia.  
- Life expectancy greater than 3 months.  
   
If the patient's condition and medical history match the allowed criteria and do not conflict with any exclusions, they may qualify for the trial despite having an ALK mutation, as long as no other specific genetic marker criteria are stipulated further in the full protocol or additional study documents. It's always advisable for the patient or their healthcare provider to discuss the specifics with the trial facilitators.