# 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:  
This trial is for Acute Myeloid Leukemia (AML) patients. The criteria mention nothing about ALK gene mutations. While some targeted therapies exist for ALK-positive cancers (typically lung cancer), this trial does not specify that ALK status is relevant for inclusion or exclusion. Therefore, having an ALK mutation doesn't automatically disqualify a patient, but they must meet all other inclusion criteria (age, AML diagnosis, performance status, etc.) and not have any of the exclusion criteria.