# Clinical Trials Data ALK - Document 24

# A Study of Different Titration Schedules of ALKS 5461 in Adults With Major Depressive Disorder (MDD)

## Clinical Trial: https://clinicaltrials.gov/study/NCT02085135

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Body mass index of 18-40 kg/m2\n\* Have a diagnosis of MDD\n\* Have a current major depressive episode (MDE) lasting 8 weeks to 24 months\n\* Have been treated with an adequate dose of an approved antidepressant during the current MDE for at least 8 weeks\n\* Have an inadequate response to current antidepressant treatment\n\* Agree to use an approved method of birth control for the duration of the study\n\* Additional criteria may apply\n\nExclusion Criteria:\n\n\* Currently pregnant or breastfeeding\n\* History of or current infection with Hepatitis B Virus, Hepatitis C Virus or Human Immunodeficiency Virus (HIV)\n\* Have experienced hallucinations, delusions, or any psychotic symptoms in the current MDE\n\* Have used opioid agonists (eg, codeine, oxycodone, tramadol, or morphine) or opioid antagonists (eg, naloxone, naltrexone) within 14 days\n\* Have received electroconvulsive therapy treatment within the last 5 years\n\* Have attempted suicide within the past 2 years\n\* Have a history of intolerance, allergy, or hypersensitivity to buprenorphine or opioid antagonists (eg, naltrexone, naloxone)\n\* Have had a significant blood loss or blood donation with 60 days of screening\n\* Additional criteria may apply",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 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 provided information does \*not\* mention ALK gene mutation status as either an inclusion or exclusion criterion. Therefore, based strictly on the information given, having an ALK mutation would \*not\* automatically disqualify a patient.   
  
However, the criteria state that "Additional criteria may apply." It is entirely possible that ALK mutation status \*is\* considered under these additional criteria, but it's not explicitly stated. Therefore, we cannot definitively say whether a patient with an ALK mutation would be eligible. More information is needed.