# Clinical Trials Data EGFR - Document 106

# A Multicenter Clinical Trial of Allopurinol to Prevent Kidney Function Loss in Type 1 Diabetes

## Clinical Trial: https://clinicaltrials.gov/study/NCT02017171

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Male or female subjects with type 1 diabetes continuously treated with insulin within one year from diagnosis\n\* Duration of T1D \u2265 8 years\n\* Age 18-70 years\n\* History or presence of microalbuminuria or moderate macroalbuminuria, or evidence of declining kidney function regardless of history or presence of albuminuria and/or RAS Blocker treatment. Micro- or moderate macroalbuminuria will be defined as at least two out of three consecutive urinary albumin excretion rates \\[AERs\\] or albumin creatinine ratios \\[ACRs\\] taken at any time during the two years before screening or at screening in the 30-5000 mg/24 hr (20-3333 ug/min) or 30-5000 mg/g range, respectively, if not on RASB agents, or in the 18-5000 mg/24 hr (12-3333 ug/min) or 18-5000 mg/g range, respectively, if on RASB agents). Evidence of declining kidney function will be defined as an eGFR (CKD-EPI) decline \u22653.0 ml/min/1.73 m2/year, estimated from the slope derived from all the available serum creatinine measurements (including the one at screening assessment) from the previous 3 years. If at least 3 serum creatinine measures are not available in the previous 3 years, then the slope can be derived from creatinine values from the previous 5 years.\n\* Estimated GFR (eGFR) based on serum creatinine between 40 and 99.9 ml/min/1.73 m2 at screening. The upper and the lower limits should be decreased by 1 ml/min/1.73 m2 for each year over age 60 (with a lower limit of 35 ml/min/1.73m2) and by 10 ml/min/1.73 m2 for strict vegans.\n\* Serum UA (UA) \u2265 4.5 mg/dl at screening\n\nExclusion Criteria:\n\n\* History of gout or xanthinuria or other indications for uric acid lowering therapy such as cancer chemotherapy.\n\* Recurrent renal calculi.\n\* Use of urate-lowering agents within 2 months before screening.\n\* Current use of azathioprine, 6-mercaptopurine, didanosine, warfarin, tamoxifen, amoxicillin/ampicillin, or other drugs interacting with allopurinol.\n\* Known allergy to xanthine-oxidase inhibitors or iodine containing substances.\n\* HLA B\\\*58:01 positivity (tested before randomization).\n\* Renal transplant.\n\* Non-diabetic kidney disease.\n\* SBP\\>160 or DBP \\>100 mmHg at screening or SBP\\>150 or DBP\\>95 mmHg at the end of the run-in period.\n\* Cancer treatment (excluding non-melanoma skin cancer treated by excision) within two years before screening.\n\* History of clinically significant hepatic disease including hepatitis B or C and/or persistently elevated serum liver enzymes at screening and/or history of HBV/HCV positivity.\n\* History of acquired immune deficiency syndrome or human immunodeficiency virus (HIV) infection.\n\* Hemoglobin concentration \\<11 g/dL (males), \\<10 g/dL (females) at screening.\n\* Platelet count \\<100,000/mm3 at screening.\n\* History of alcohol or drug abuse in the past 6 months.\n\* Blood donation in the 3 months before screening.\n\* Breastfeeding or pregnancy or unwillingness to be on contraception throughout the trial.\n\* Poor mental function or any other reason to expect patient difficulty in complying with the requirements of the study.\n\* Serious pre-existing medical problems other than diabetes, e.g. congestive heart failure, pulmonary insufficiency.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

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

Answer:  
This trial is specifically for patients with \*\*type 1 diabetes\*\* and related kidney issues. The inclusion criteria mention nothing about EGFR gene mutations. Therefore, having an EGFR mutation does \*not\* automatically qualify or disqualify someone. They would need to meet \*all\* of the other inclusion criteria (related to diabetes, kidney function, etc.) and \*none\* of the exclusion criteria to be eligible.