# Clinical Trials Data KIT - Document 46

# Strategies and Opportunities to Stop Colon Cancer in Priority Populations

## Clinical Trial: https://clinicaltrials.gov/study/NCT01742065

"detailedDescription": "Phase I (Pilot Aims)\n\n\* Aim 1 Conduct preliminary analyses of EHR data at two pilot clinics.\n\* Aim 2: Use codes and methods developed in Aim 1 to test the feasibility, reach, effectiveness, and cost of an EHR-based CRC screening intervention using a subset of 100 patients at each of two pilot clinics. We will use codes defined in Aim 1 to create a Solutions-based, Epic-integrated system to track CRC screening, mail FIT kits, and track patient test results and receipt of follow-up care. The system will be pilot-tested in two clinics.\n\* Aim 3: Use results from the pilot intervention to prepare for a large-scale, cluster-randomized pragmatic trial across 18 OCHIN clinics (see Phase II).\n\nTransition from Phase I to Phase II\n\n-Changes to our original proposal include going from a three arm to a two-arm pragmatic cluster trial with revised evaluation and power calculation and refinements to the intervention components for both usual care (now described as enhanced usual care) and the intervention (now described as enhanced auto).\n\nPhase II (Full trial Aims)\n\n\* Primary Aim 1. Assess the effectiveness of a large-scale, two-arm CRC screening program among diverse CLINIC patients, and assess difference in CRC screening outcomes (overall and by age, sex, insurance status, Hispanic ethnicity/race). The intervention will consist of an automated data-driven, EHR-linked program for mailing FIT kits (with linguistically appropriate pictographic instructions and return postage) to patients due for CRC screening.\n\* Primary Aim 2. Assess the costs and long-term cost-effectiveness of the automated program.\n\nWe have also included two secondary aims:\n\n\* Secondary Aim 1. Assess adoption, implementation, reach and potential maintenance and spread of the program, using a mixed-method rapid assessment process, field notes, and other ethnographic data.\n\* Secondary Aim 2. Adapt and pilot-test the adaptation of STOP CRC in an alternate EHR platform, Allscripts, and develop an implementation guide to assist sites in adopting the program."  
 "eligibilityCriteria": "Inclusion Criteria:\n\n\* Patients aged 50-74 with no evidence of a colonoscopy within 9 years or fecal testing within 11 months, and no history of colorectal disease will be eligible to receive a mailed FIT.\n\nExclusion Criteria:\n\n\* End Stage Renal Disease (ESRD)\n\* Hospice/Nursing Home",  
 "healthyVolunteers": true,  
 "sex": "ALL",  
 "minimumAge": "50 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]  
 "nonInferiorityComment": "To assess effectiveness, we fit generalized estimating equations (GEE) with a logistic link to model patient-level data. We weighted patient data so that each clinic's data had an equal weight. Models were adjusted for age, sex, and health center. They used robust variance estimators and independent correlation structures. We specified clinic as a clustering variable to account for intraclinic correlation; the intraclinic correlation coefficient was 0.05 after model covariates adjustment.",  
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Question:  
Based on the following clinical trial information, would a patient with a KIT gene mutation be eligible for the clinical trial?

Answer:  
Based on the information provided, the clinical trial is focused on CRC (colorectal cancer) screening using mailed FIT (fecal immunochemical test) kits. The eligibility criteria for the trial include:  
  
\*\*Inclusion Criteria:\*\*  
- Patients aged 50-74  
- No evidence of a colonoscopy within 9 years  
- No fecal testing within 11 months  
- No history of colorectal disease  
  
\*\*Exclusion Criteria:\*\*  
- End Stage Renal Disease (ESRD)  
- Hospice/Nursing Home  
  
There is no mention of a KIT gene mutation as part of the inclusion or exclusion criteria. Therefore, a patient with a KIT gene mutation would be eligible for the trial as long as they meet the age criteria, have no recent colonoscopy or fecal testing, have no history of colorectal disease, and do not have ESRD or are not in hospice/nursing home care.