# Clinical Trials Data KIT - Document 27

# Colorectal Cancer Awareness, Research, Education and Screening (CARES)

## Clinical Trial: https://clinicaltrials.gov/study/NCT01804179

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Racially-ethnically diverse adult men and women\n\* Average risk individuals who have no personal diagnosis, or presumptive symptoms of colorectal cancer (CRC), or are not at high risk\n\* Self-report as not current on screening\n\* Provide at least two forms of contact information and contact information of a relative (not living with respondent) to facilitate follow-up contacts\n\* Are able to speak, read and write English because the instruments and CARES intervention are available only in English at this time. We recognize that interventions are needed for non-English speaking populations, therefore, once we find promise in the English language CARES intervention materials, we will move forward with conducting other studies that involve translation of measures and cultural adaptation of the CARES intervention materials into Spanish or Haitian Creole.\n\nExclusion Criteria:\n\n\* Individuals who have participated in a CRCS research study in the past 1 year will not be eligible for this study.\n\* Recent screening criteria relates to not having had I-FOBT within the previous year, flex sig within the previous 5 years, a double-contrast barium enema (DCBE) x-ray with the previous 5 years, or a colonoscopy within the previous 10 years.\n\* Within the recruitment and intervention frame, high risk individuals (due to strong family history, ulcerative colitis, polyposis syndromes) are excluded because they may be eligible for CRC screening before age 50, and the preferred screening option is certainly colonoscopy which is beyond the primary focus of the current study.",  
 "healthyVolunteers": true,  
 "sex": "ALL",  
 "minimumAge": "50 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

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

Answer:  
This trial is for colorectal cancer screening in average-risk adults. The inclusion/exclusion criteria focus on screening history and current risk factors, not genetic predispositions. While having a KIT gene mutation \*can\* increase the risk of certain cancers, including gastrointestinal stromal tumors (GIST), it's not specifically mentioned. Therefore, having a KIT mutation doesn't automatically exclude someone, but it doesn't automatically qualify them either.  
  
\*\*Here's why a patient with a KIT mutation might be EXCLUDED:\*\*  
  
\* \*\*If the KIT mutation is associated with a family history of cancers that puts them in a high-risk category for CRC:\*\* The exclusion criteria specifically mention excluding individuals at high risk due to family history. If the patient's KIT mutation contributes to such a family history, they would likely be ineligible.  
\* \*\*If the KIT mutation requires earlier or more frequent colonoscopies:\*\* The study is aimed at average-risk individuals who are not yet getting regular colonoscopies. If the KIT mutation necessitates a different screening regimen, the patient would not fit the target population.  
  
\*\*Here's why a patient with a KIT mutation might be INCLUDED:\*\*  
  
\* \*\*If the KIT mutation is \*not\* associated with a family history of CRC and the individual is otherwise average-risk:\*\* In this case, the patient would likely meet the inclusion criteria, provided they also fulfill the other requirements (age, screening history, etc.).  
  
\*\*In summary:\*\* The patient needs to discuss their KIT mutation with their doctor and the study investigators to determine if their specific situation makes them eligible or ineligible for this particular trial. The presence of the mutation itself is not the sole deciding factor.