

FORTE

live enE

A COLORECTAL CANCER PREVENTION TRIAL

Five- or Ten-Year Colonoscopy for 1-2 Non-Advanced Adenomatous Polyps

NRG Oncology NCORP (National Cancer Institute [NCI] Community Oncology Research Program) is thrilled to announce that the NRG-CC005/FORTE study protocol and consent have been approved by the NCI Division of Cancer Prevention (DCP) and Central Institutional Review Board (CIRB). ***The FORTE study leadership team is anticipating activation this summer.***

As the practice of colonoscopy expands to include the vast majority of adults and the detection of an adenoma at colonoscopy increases, the inconvenience, medical risk, and resources associated with and devoted to follow-up surveillance colonoscopy for these adenomas will greatly increase. Research to determine the benefit and yield of surveillance colonoscopy in patients with non-advanced adenomas is a high priority. A randomized, clinical trial to evaluate the difference in yield between 5 and 10 years vs. 10-year surveillance for participants with non-advanced adenoma is needed to guide clinical practice. The FORTE study will evaluate the need for repeated colonoscopy procedures. Your support and involvement with the trial is critical to its success.

NRG-CC005 is a prospective, randomized, non-blinded, phase III, non-inferiority clinical trial conducted by NRG Oncology. Participants with 1-2 non-advanced adenomas will be randomized to the recommendation for 10-year surveillance colonoscopy vs. 5- and 10-year surveillance. Randomization will be 1:1. The primary aim of the study is a comparison of the incidence of colorectal cancer in the two arms.

FORTE is part of the NCI NCORP structure. The trial will be led by NRG Oncology with the participation of the National Clinical Trials Network (NCTN) organizations: Alliance for Clinical Trials in Oncology, ECOG-ACRIN Cancer Research Group, and SWOG.

The study team encourages sites to begin pre-launch preparations to participate in this colorectal cancer prevention study. Identify your research study staff, establish potential collaborations with colonoscopists in your institution and community, and develop plans for implementation to facilitate recruitment.

As you plan to build your FORTE network, consider the following:

Investigator/Research Staff

Investigators consenting study participants must be rostered at the enrolling site with CTEP (Cancer Therapy Evaluation Program). However, physicians and endoscopists that refer participants to a study center/site(s) are NOT required to be registered. With this in mind,

- Identify a Principal Investigator
- Identify the dedicated research staff, and confirm that these people are currently registered with an IAM/CTEP account and CTSU Medidata Rave Access
- Identify physician groups who may be interested in participating in the FORTE study. Develop plans for facilitating patient referrals for possible trial enrollment. Provide your contact information as the NRG research staff responsible for screening and enrollment to the FORTE trial.
- Develop plans for the process of participant enrollment and consent.

Identifying Potential Participants

- What mechanisms exist to identify patients both retrospectively (databases of completed colonoscopies) or prospectively as colonoscopies occur?
- Check to see if databases of previously completed procedures are available or whether reports can be assembled and then subjected to Natural Language Processing (NLP) to identify patients who meet the inclusion criteria.

If you have questions about the NRG-CC005 / FORTE study, please contact the Clinical Coordinating Department (CCD) at ccdpg@nrgoncology.org or (800) 477-7227.