FAST FACTS

ALLIANCE A212101 - EVALUATION OF PROVIDER VS. PATIENT MEDIATED CASCADE GENETIC TESTING OF FIRST-DEGREE RELATIVES OF PATIENTS WITH NEWLY DIAGNOSED COLORECTAL CANCER

3.0 PATIENT SELECTION

There are two study populations for this trial: 1) Probands will be newly diagnosed cancer patients, and 2) the proband's first-degree relatives, referred to as "FDRs," throughout the protocol.

3.1 Step 1 Eligibility Criteria (Probands)

1. Age ≥ 18 years

2. Patients with a newly diagnosed (within 3 months of registration), primary colorectal adenocarcinoma, Stage I to IV
    - Histologically proven Stage I to IV colon or rectal adenocarcinoma (any T or N, M+). Tumors deemed to originate in the colon can extend into/involve the small bowel (e.g., those at the ileocecal valve). Tumors will be regarded as originating in the colon if the entire tumor is in the colon. In the case of rectal involvement, the cancer will be considered a rectal primary.
    - Patients with more than one primary colon adenocarcinoma are eligible

3. No patients with Stage 0 or in-situ colorectal cancer

4. Patients who have had prior malignancies are eligible, including non-invasive cancers.

5. Patients with synchronous second malignancies are eligible.

6. Have not received germline testing in the 2 years prior to enrollment or known hereditary colon cancer syndromes

7. Patients must have at least 2 living FDRs who meet the eligibility criteria in Section 3.3, with whom the patient is willing to share their cancer diagnosis.

8. Language - In order to complete the mandatory patient-completed measures and view the video and receive genetic education and counselling, participants must be able to speak and read English or Spanish.

9. No known diagnosis of dementia or cognitive impairment. Persons with impaired decision-making capacity are ineligible as they need to be able to understand genetic test results, its implications for the patient and family, and explain genetic test results to their family members.

    No persons with a known psychiatric or documented developmental disorder that affects cognitive or emotional functions to the extent that the capacity for judgment and reason is significantly diminished, such that they cannot participate based on the judgment of the treating physician.

3.2 Step 2 Eligibility Criteria (Probands)

1. Probands positive for a pathogenic germline variant (PGV) in a cancer susceptibility gene

3.3 Eligibility Criteria for FDRs

1. Age ≥ 18 years

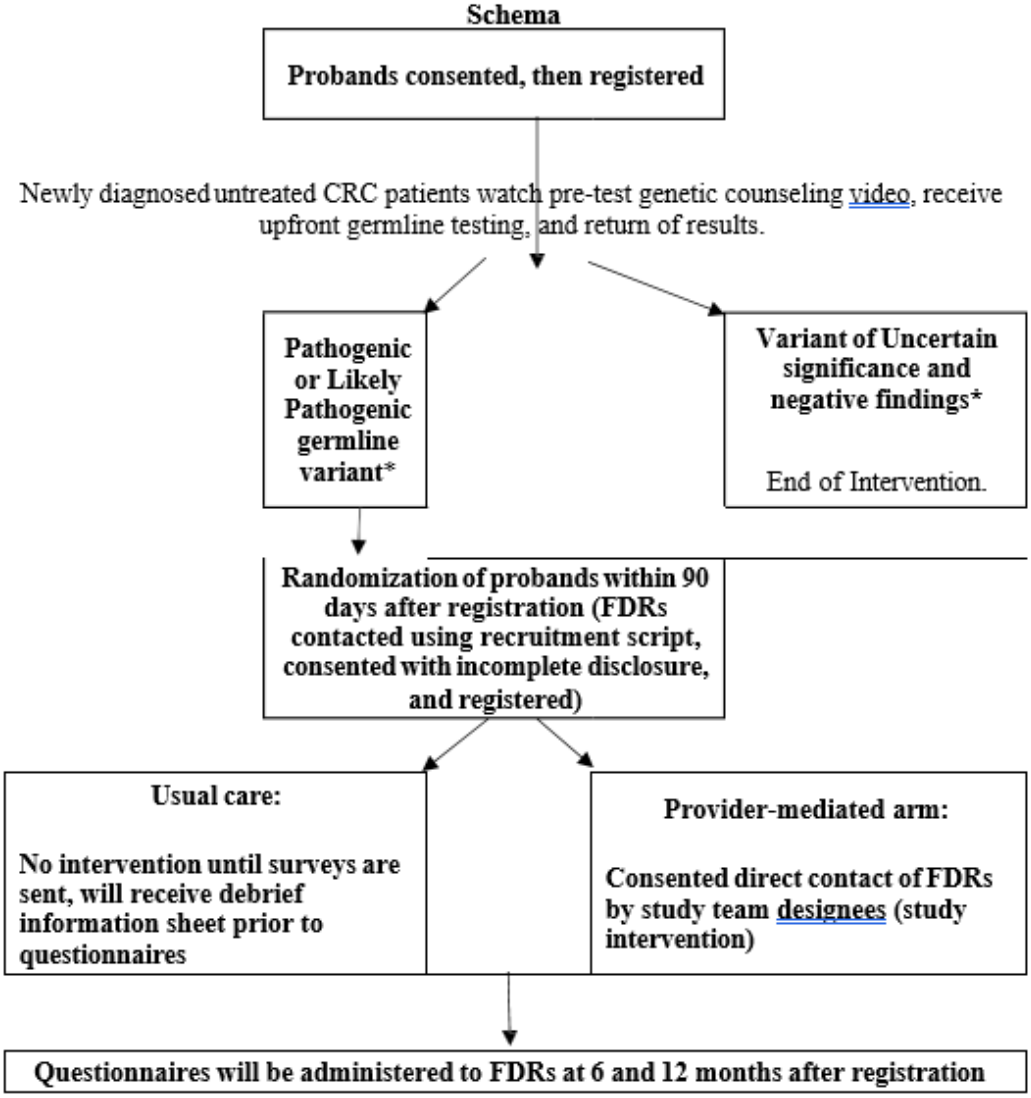
2. Have not previously received germline genetic testing or known hereditary colon cancer syndromes

3. FDRs must reside within the United States, as genetic testing from LabCorp is only available to U.S. residents.

4. Language - In order to complete the mandatory patient-completed measures, participants must be able to speak and read English or Spanish.

Study populations: There are two study populations for this trial: 1) **Probands** will be newly diagnosed cancer patients, and 2) the proband's **first-degree relatives**, referred to as "FDRs," throughout the protocol.

Schema



*All probands will be followed for survival for up to 3 years after registration and be asked to participate in optional translational research (see Section 6.2).