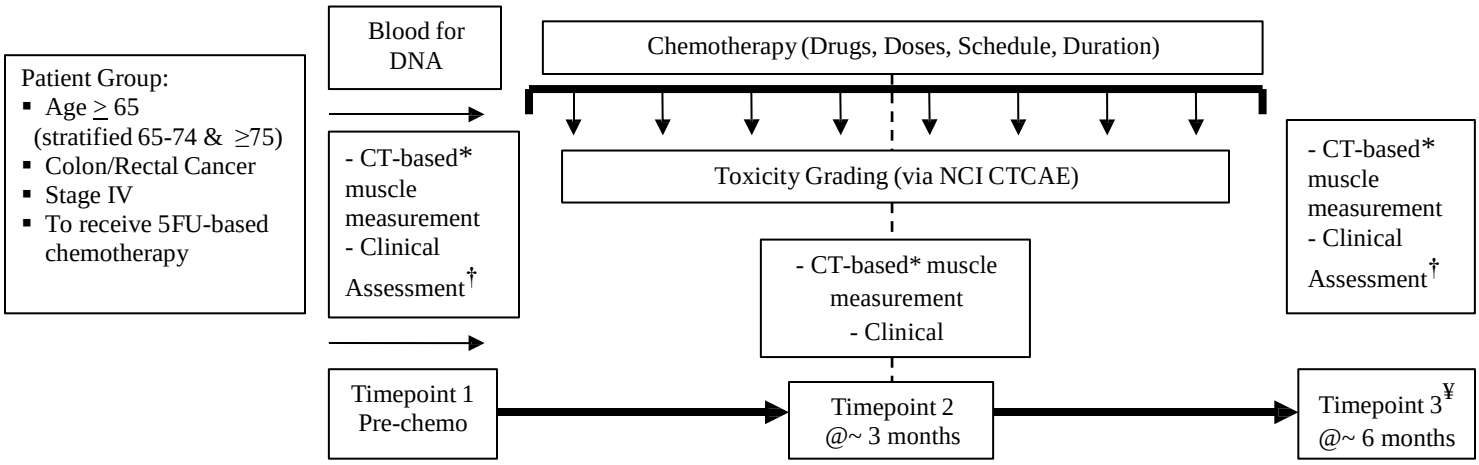
SCHEMA

Study Design: This is a prospective cohort study that examines the impact of myopenia on chemotherapy toxicity and overall survival (OS) in older adults with newly diagnosed metastatic colorectal cancer (CRC) or newly recognized metastatic recurrence for CRC greater than 1 year from completion of treatment of non-metastatic CRC planning to receive systemic chemotherapy. The study also explores the moderating influence of genetic variation in the association between myopenia and chemotherapy toxicity.



*CT imaging is performed as part of routine care at baseline and every ~12 weeks during chemotherapy to assess disease response.
†Clinical assessments include muscle strength, physical performance, questionnaire assessments, and PRO-CTCAE toxicity assessments.
¥ Patients will be followed up to 1 year after diagnosis for survival only.

Stratification: In order to ensure a wide range in body composition and a diverse sample of older adults, enrollment will be equally distributed across two age strata: 65-74yo and ≥75yo.

Study Sample: n=300 (150 patients per age stratum)

Study Duration: 3.5 years

Brief Eligibility Criteria:

1) Older adults (age ≥ 65y) with either newly diagnosed metastatic CRC or newly recognized metastatic recurrence of CRC greater than 1 year from completion of treatment of non-metastatic CRC

2) Scheduled to undergo 1st line 5-FU based chemotherapy (as monotherapy [5-FU alone or capecitabine] or in combination with oxaliplatin and/or irinotecan +/- biologics)

3) Estimated life expectancy ≥6 months. Patients enrolled on hospice are ineligible.

4. PARTICIPANT SELECTION

4.1 Inclusion Criteria

4.1.1 Older adults (age ≥ 65y) with either
- newly diagnosed metastatic CRC or
- newly recognized metastatic recurrence of CRC greater than 1 year from completion of treatment for non-metastatic CRC

4.1.2 Planning to undergo 1st line 5-FU based chemotherapy (as monotherapy [as 5-FU alone or capecitabine] or in combination with oxaliplatin and/or irinotecan +/- biologics).

4.1.3 Estimated life expectancy ≥ 6 months.

4.1.4 Patients must be able to read and comprehend English or Spanish (for questionnaire completion).

4.1.5 Ability to understand and the willingness to sign a written informed consent document.

4.1.6 Patient eligibility is not dependent on BMI or weight. Patients with a significant (± > 10%) body weight change in the previous 12 months are eligible for this study.

4.2 Exclusion Criteria

4.2.1 Patients enrolled on hospice.

4.2.2 Prior systemic chemotherapy for metastatic colorectal cancer (acceptable if adjuvant chemotherapy completed ≥12 months prior to disease recurrence).

4.2.3 Patients may not be receiving any other investigational agents.

4.2.4 No untreated brain metastases. Patients with treated brain metastases are eligible.

4.3 Inclusion of Women and Minorities

Both men and women (as applicable) and members of all races and ethnic groups are eligible for this trial. All questionnaires will be available in English and Spanish. We will encourage participating practices to approach all potentially eligible patients, regardless of gender or race/ethnicity.