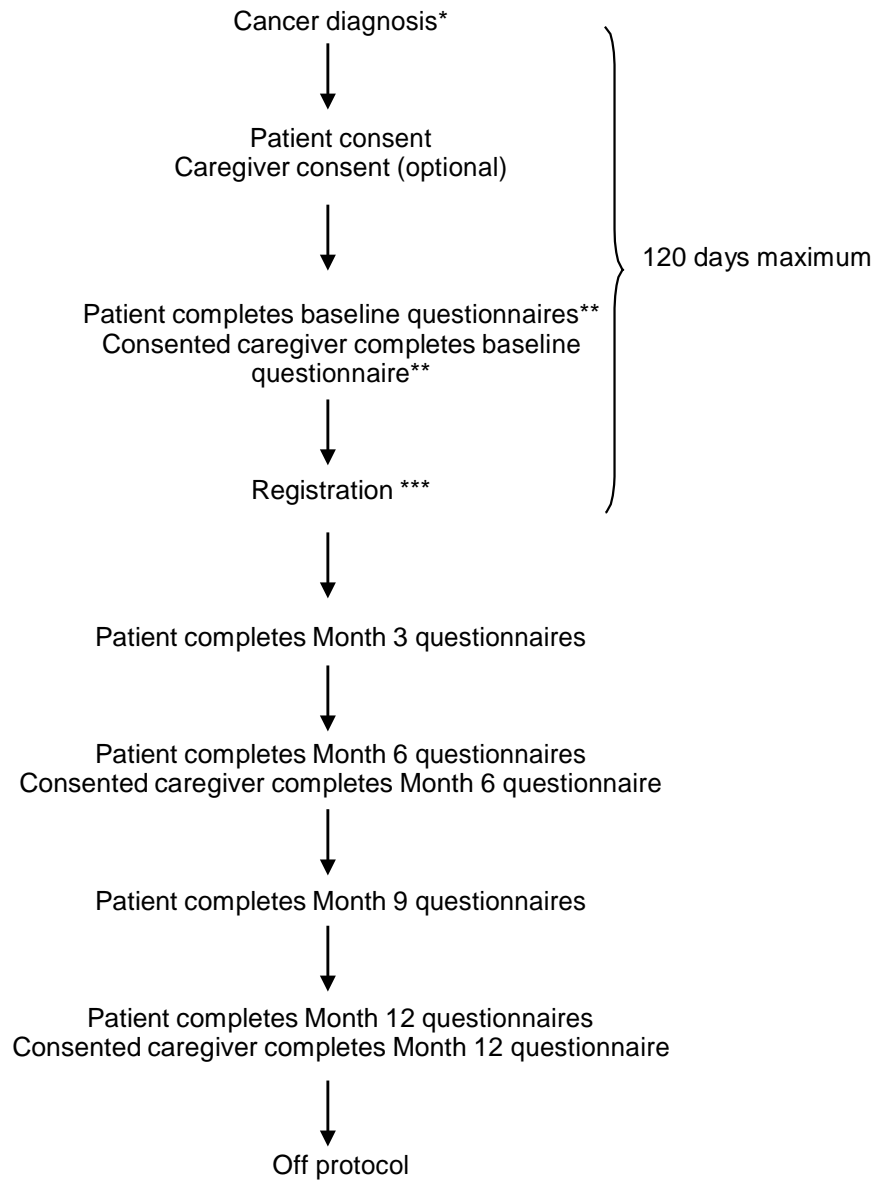


SCHEMA FOR FLOW OF STUDY



* Patients must have newly diagnosed metastatic colon or rectal cancer (de novo metastatic diagnosis or metastatic recurrence after prior treatment for Stage I-III disease) at registration and be within 120 days after diagnosis.

** Patient and caregiver may complete baseline questionnaires at any time following consent. Questionnaires are to be submitted within 7 days after registration. Caregiver participation is optional.

*** Systemic chemotherapy and/or systemic biologic therapy must be planned to be administered ≤ 30 days after registration or must have been initiated ≤ 60 days prior to registration.

3.0 ELIGIBILITY CRITERIA

Each of the criteria in the following section must be met in order for a patient to be considered eligible for registration. Any potential eligibility issues should be addressed to the SWOG Statistics and Data Management Center in Seattle at 206/652-2267 or cancercontrolquestion@crab.org prior to registration. NCI policy does not allow for waiver of any eligibility criterion (https://ctep.cancer.gov/protocolDevelopment/policies_deviations.htm).

When calculating time frame for date of diagnosis, the date that the pathological diagnosis was made is considered Day 0. **If Day 30 or 120 falls on a weekend or holiday, the limit may be extended to the next working day.**

3.1 Disease Related Criteria

- a. Patients must have newly diagnosed metastatic colon or rectal cancer (mCRC) (de novo metastatic diagnosis) or metastatic recurrence after prior treatment for Stage I-III disease and be \leq 120 days after diagnosis at time of registration.
- b. Systemic chemotherapy and/or systemic biologic therapy must be planned to be administered \leq 30 days *after* registration OR must have been initiated \leq 60 days *prior* to registration. Patients who are planning palliative or hospice care only (no chemotherapy or biologic therapy) are not eligible.

3.2 Clinical Criteria

- a. Patients must be at least 18 years of age.

3.3 Regulatory Criteria

- a. Registering site must be an NCORP site.

NOTE: It is recommended that patients receive medical care for the mCRC at the registering site to ensure accessibility of patient records.

- b. Patients must be able to complete questionnaires in English.
- c. Patients must provide their full name, primary address in the U.S., birth date and social security number at registration for the purposes of accessing credit report data.
- d. Patients must sign and give written informed consent in accordance with institutional and federal guidelines.
- e. As a part of the OPEN registration process (see Section 8.0 for OPEN access instructions) the treating institution's identity is provided in order to ensure that the current (within 365 days) date of institutional review board approval for this study has been entered in the system.