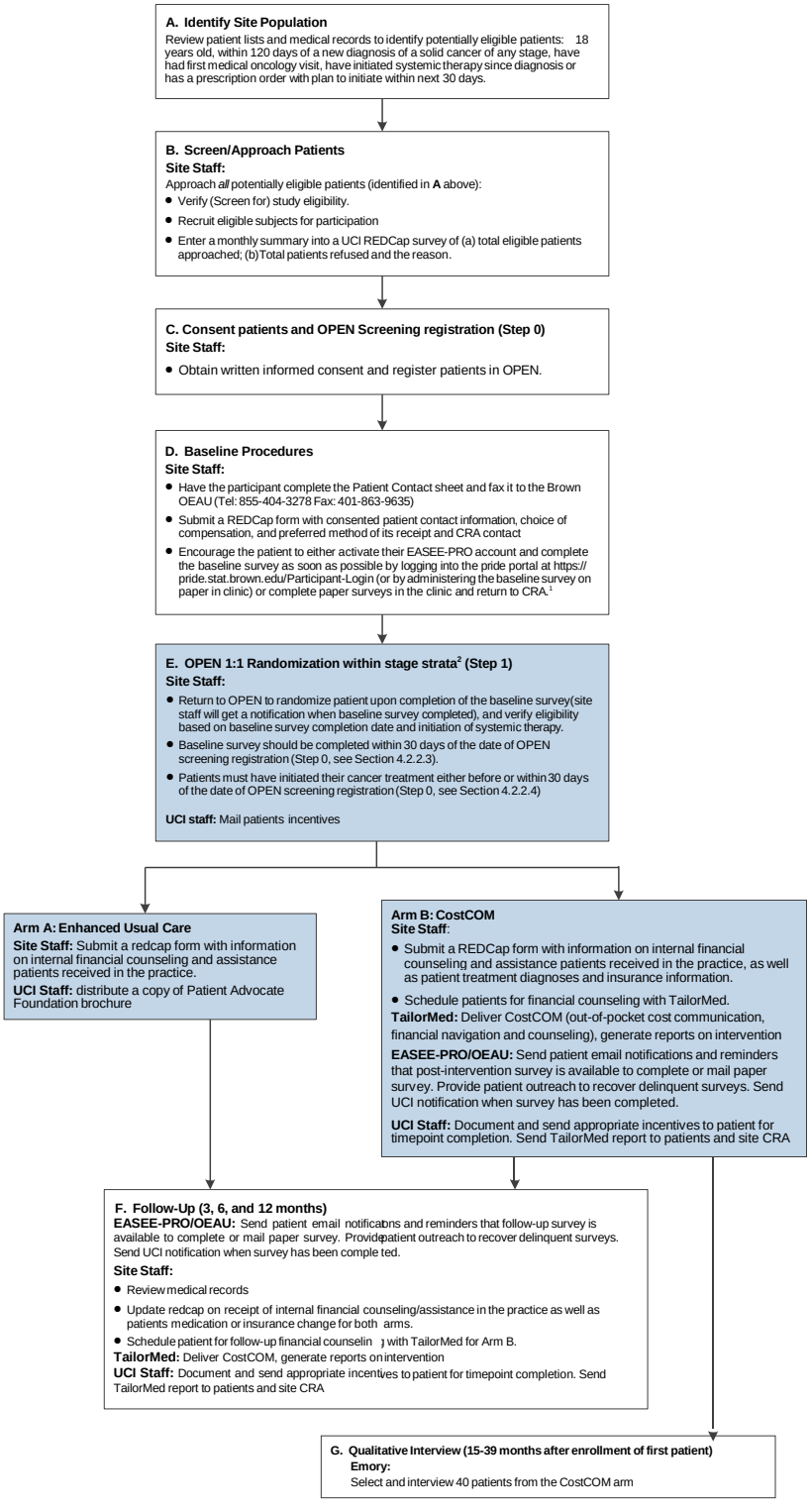
Patient Schema



Footnote: Please note the study sample size is recruitment of 720 patients to Step 1.

1. It is encouraged for completion of consent, baseline survey, and randomization to occur on the same day.
2. Stage stratification is based on early vs. metastatic stage.

4. Selection of Participants

4.1 Non-Patients Participants

To achieve Aim 3, we will enroll a subset of providers (n=approximately 40) from a minimum of 15 participating NCORP subsites. These providers will include:

1. study coordinators with a role involving use of CostCOM intervention price transparency and financial navigation platform (n=approximately 15),
2. oncology provider with patients, assigned to the CostCOM arm, that completed at least 6 months follow-up study (n=approximately 15), and
3. practice financial counselors, social workers, financial navigators, or pharmacist with a role in helping with co-pay assistance in at least one patient assigned to CostCOM arm (n=approximately 10).

4.1.1 Non-patient participants Eligibility Criteria

_____ 4.1.1.1 Participant must speak English.

_____ 4.1.1.2 Participant must be employed at NCORP site for at least six months.

_____ 4.1.1.3 Participant must be able to provide informed consent to participate in this study.

_____ 4.1.1.4 Participant must be one of the following:

1. a study coordinator with a role involving use of CostCOM intervention price transparency and financial navigation platform,
2. a practice oncology provider (i.e., physician or mid-level), or
3. a practice financial counselor, social workers, financial navigators, or pharmacist

who have provided care or been in contact (in the last 3 months) to a patient who was assigned to the CostCOM arm, and who completed at least 6 month study follow-up.

4.2 Patient Eligibility Criteria

Each of the criteria in the checklist that follows must be met in order for a patient to be considered eligible for this study. Use the checklist to confirm a patient's eligibility. For each patient, this checklist must be photocopied, completed and maintained in the patient's chart.

In calculating days of tests and measurements, the day a test or measurement is done is considered Day 0. Therefore, if a test is done on a Monday, the Monday four weeks later would be considered Day 28.

ECOG-ACRIN Patient No. _____

Patient's Initials (L, F, M) _____

Physician Signature and Date _____

NOTE: CTEP Policy does not allow for the issuance of waivers to any protocol specified criteria

(http://ctep.cancer.gov/protocolDevelopment/policies_deviations.htm). Therefore, all eligibility criteria listed in Section 4 must be met, without exception. The registration of individuals who do not meet all criteria listed in Section 4 can result in the participant being censored from the analysis of the study, and the citation of a major protocol violation during an audit, and require reporting to the IRB of record as non-compliance.

All questions regarding clarification of eligibility criteria must be directed to the Group's Executive Officer (EA.ExecOfficer@jimmy.harvard.edu) or the Group's Regulatory Officer (EA.RegOfficer@jimmy.harvard.edu).

NOTE: Institutions may use the eligibility checklist as source documentation if it has been reviewed, signed, and dated prior to registration/randomization by the treating physician.

4.2.1 Patient Eligibility Criteria for Step 0 (OPEN Screening Registration)

_____ 4.2.1.1 Patient must be ≥ 18 years of age.

_____ 4.2.1.2 Patient must be fluent in written and spoken English

OR

Patient must be fluent in written and spoken Spanish

_____ 4.2.1.3 Patient must be within 120 days of a new diagnosis of any solid cancer of any stage at the time of Step 0.

_____ 4.2.1.4 Patient must have had their first medical oncology visit at the time of Step 0.

_____ 4.2.1.5 Patient must have initiated oral or IV cancer systemic therapy or have received a prescription order with stated intent to initiate within 30 days following Step 0 consent.

_____4.2.1.6 Patients must not have indolent cancer undergoing observation alone (i.e., active surveillance).

_____ 4.2.1.7 Patients must not be receiving palliative or hospice care alone.

_____ 4.2.1.8 Patient must not be undergoing curative surgery alone or radiation therapy alone. (Must be receiving systemic therapy), unless they are receiving systemic therapy.

_____ 4.2.1.9 Patient must confirm that they intend to receive their care or monitoring at one of the participating NCORP practices.

_____ 4.2.1.10 Patient must have the ability to understand and the willingness to sign a written informed consent document.

NOTE: Patients with impaired decision-making capacity (IDMC) who have a legally authorized representative (LAR) or caregiver and/or family member available are not eligible.

_____4.2.1.11 Patient must not have an ECOG Performance Status ≥ 3.

OR

Patient must not be deemed medically unable to participate in the study by the study investigators or an oncology clinician (i.e., referral to hospice).

_____ 4.2.1.12 Patient must not be enrolled in treatment clinical trials where cancer systemic therapy is provided at no cost to the patient.

_____ 4.2.1.13 Patient must not be enrolled in EAQ221CD or S1912CD given financial navigation is offered as part of these two trials.

NOTE: If S1912CD is activated in a participating practice, S1912CD should be offered first to patients with metastatic cancer meeting eligibility criteria for S1912CD. Only if a patient is not eligible or not interested in participating in S1912CD, the EAQ222CD can be offered. For early stage cancer, EAQ222CD can be offered first given S1912CD does not enroll patients with early stage cancer.

_____ 4.2.1.14 Patient must not be enrolled in other clinical trials where OOPC communication or financial navigation (i.e., professional guidance to identify financial assistance programs to alleviate cost of care) is being offered as part of the trial.

NOTE: If a trial is offering financial counseling alone without financial navigation patients are allowed to co-enroll.

NOTE: Gift cards for survey completion, or parking passes are not considered financial navigation.

4.2.2 Patient Eligibility Criteria for Step 1 (OPEN Randomization)

_____ 4.2.2.1 Patient must meet all the eligibility criteria for Step 0 outlined in Section 4.2.1.

_____ 4.2.2.2 Patient must have signed a written informed consent form.

_____ 4.2.2.3 Patient must have a completed Baseline Survey in EASEE-PRO within 30 days of the date of OPEN screening Registration (Step 0).

_____ 4.2.2.4 Patients must have initiated their cancer treatment (i.e., IV or Oral systemic therapy) either before or within 30 days of the date of OPEN screening Registration (Step 0).

_____ _____

Physician Signature Date

OPTIONAL: This signature line is provided for use by institutions wishing to use the eligibility checklist as source documentation.