# **FAST FACTS**

# EAQ22CD: Effectiveness of Out-of-Pocket Cost COMmunication and Financial Navigation (CostCOM) in Cancer Patients

# **ELIGIBILITY CRITERIA**

# **Inclusion Criteria**

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

- 1. Patient must be  $\geq$  18 years of age.
- Patient must be fluent in written and spoken English
   OR
   Patient must be fluent in written and spoken Spanish
- 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. Patient must have had their first medical oncology visit at the time of Step 0.
- 5. Patient must have initiated oral or IV cancer systemic therapy either any time before Step 0 registration or have received a prescription order with stated intent to initiate within 30 days following Step 0 registration.
- Patients must not have indolent cancer undergoing observation alone (i.e., active surveillance).
- 7. Patients must not be receiving palliative or hospice care alone.
- 8. Patient must not be undergoing curative surgery alone or radiation therapy alone. (Must be receiving systemic therapy), unless they are receiving systemic therapy.
- 9. Patient must confirm that they intend to receive their care or monitoring at

one of the participating NCORP practices.

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.

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).

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

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.

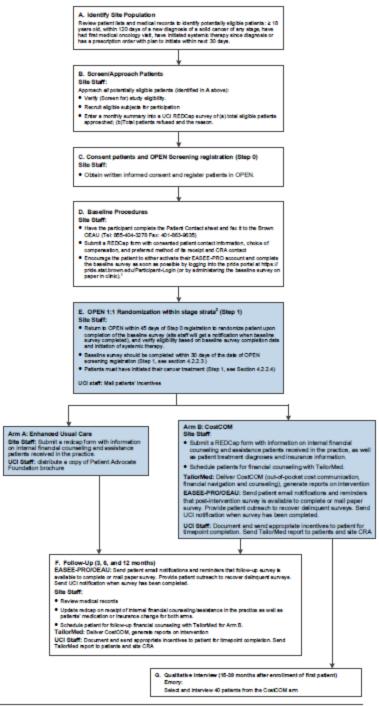
**NOTE:** Gift cards for survey completion, or parking passes are not considered financial navigation.

# Patient Eligibility Criteria for Step 1 (OPEN Screening Registration)

- 1. Patient must meet all the eligibility criteria for Step 0 outlined in Section 4.2.1.
- 2. Patient must have signed a written informed consent form.
- 3. Patient must have a completed Baseline Survey within 30 days of the date of OPEN screening Registration (Step 0).
- 4. Patients must have initiated their cancer treatment (i.e., IV or Oral systemic therapy).

**NOTE:** Step 1 registration must be within 45 days of Step 0 registration.

## Patient Schema



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

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

## Non-Patient Participants' Intervention Schema

### A. Identify Trigger Population:

Beginning 15 months after the first accrued at each site and every 3 months thereafter, Emory/UCI will provide each NCORP site with a list of patient IDs who were assigned to the CostCOM arm and completed at least the 6-month study follow-up.

## B. Identify and Approach Non-Patient Candidate:

NCORP staff will identify non-patient participant candidates meeting study criteria who have provided care or been in contact (in the last 3 months) with the provided patient IDs.

A UCI REDCap survey will be distributed by NCORP designee to the pool of identified non-patient participants regardless of their prior participation in the survey or interview.

### C. Consent and OPEN Registration:

- Candidates who indicate an interest in participating in an interview in the survey will continue to the e-consent process.
- Candidates consenting to the study will be added to the pool of interested, eligible and e-consented candidates.
- UCI will provide NCORP staff with a list of e-consented candidates (not previously registered in OPEN) to register in OPEN
- NCORP staff will provide UCI with a corresponding subject ID.

## D. Schedule Interviews:

Emory/UCI team will schedule the interviews.

#### E. Conduct Interviews:

Emory/UCI team will conduct the interviews.