

# **EAQ202**



## <u>Please Enroll</u> <u>Your Eligible</u> Patients!

# For Adolescents/Young Adults with Primary Cancer

### **EAQ202 Available Through ECOG-ACRIN Cancer Research Group**

Improving Adolescent and Young Adult Self-Reported Data in ECOG-ACRIN Trials

#### **Patient Population**

See Section 3 for complete eligibility criteria

<u>Selection of Sites</u>: all interested NCTN, LAPS, and NCORP sites will be invited to participate (with a focus on MU NCORP sites)

#### **Selection of Participants:**

Upon activation of Add. #5, only patients who selfidentify as BIPOC (black, indigenous, Latinx and other people of color) will be eligible for EAQ202

- Must be  $\geq$  18 years and  $\leq$  39 years of age
- Must have histologically confirmed diagnosis of primary cancer of any stage within 84 days of registration
- Must not have a recurrence or second primary cancer
- Must not have basal cell skin carcinoma
- Must have received, be currently receiving, or planning to receive treatment for cancer, including surgery and/ or chemotherapy and/or radiation therapy
- Must have an ECOG PS 0-3
- Must have a life expectancy > 24 months
- Must be able to complete questionnaires in English or in Spanish
- Must have internet access through computer, tablet, or smartphone
- Must have an email address; must have a mobile phone with text messaging capabilities
- Must be able to accurately provide self-report data (e.g. per clinical judgement, cognitive function is intact)
- Must be able to provide informed consent
- Participants may be dually enrolled in EAQ202 and therapeutic trials, including those involving checkpoint inhibitors

Note- The following cohorts are closed:

- Breast cancer (as of 09/07/22)
- Leukemia/lymphoma (as of 10/14/23)
- White non-Hispanic (as of 05/01/23)

#### Methodology Plan

See Section 5 for methodology details; Sections 6 & 8 for site completed form details; Section 7 for questionnaire details

- This is a two arm, randomized clinical trial that will explore the feasibility of measuring HRQOL among AYAs treated for cancer in academic and community settings
- Each participating site will complete one site survey, and one clinical form (per participant, per time point)
- The designated site CRN/CRA will work with physicians during the clinical session to identify/recruit patients
- Participants will be randomized (stratified by sex, age, race and ethnicity) and will rank the 15 domains from most to least important
  - ♦ Those assigned to the Choice PRO intervention arm will identify 5 (of the 15) HRQOL domains to complete at each time point
  - AYAs assigned to the Fixed PRO control arm will have domain-specific HRQOL measures fixed at each assessment (physical function, pain, cognitive function, social support, finances)
- Questionnaires will range from 82-112 items and can be completed in 13-18 minutes
  - ♦ These will be completed online through EASEE-PRO
    - Participant characteristics, feasibility and acceptability items, health literacy, Global HRQOL (PROMIS), domain-specific HRQOL, service utilization and financial impact, AYA PRO feedback
- Patients will receive surveys at 5 time points over 12 months: baseline, 1 month, 3 months, 6 months, 12 months (all +/- 2 weeks); there is no further follow-up

# Study Chair:

John M. Salsman, PhD

#### Co-Chairs:

Lynne I. Wagner, PhD Ruth C. Carlos, MD Ilana Gareen, PhD Shira N. Dinner, MD

## Patient Enrollment (Oncology Patient Enrollment Network [OPEN])



https://open.ctsu.org/open



1-888-823-5923

**Protocol Information (ECOG-ACRIN Operations – Boston)** 



http://ecog-acrin.org (Member Login)



1-857-504-2900

Schema

# **EAQ202**

diagnosis

Stratified by sex, race, ethnicity, and age (emerging adults

Fixed PRO:

PROMIS Global, PROMIS standard AYA 5 domains, Common

Participant Ranks Domain by personal priority at each time point

-Performance Status 0-3

Any stage of cancer
Favorable prognosis

year-old)

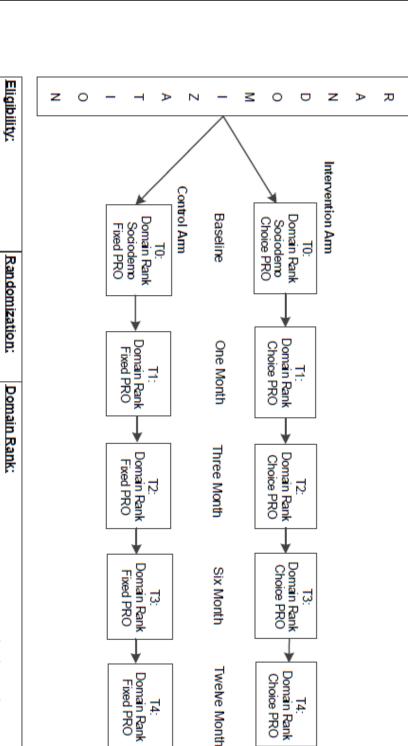
18-25-year-old vs young adults 26-39-

Choice PRO:

PROMIS Global, 5 ranked AYA domains, Common Items

-Within 12 weeks of

-Age 18 to 39



# Accrual Goal = 500

Amendment 2 increases the sample size to 500 with 100 additional BIPOC enrollees