NCI Community Oncology Research Program

EAQ221CD/CONCURxP

For Patients with HR+ HER2- Metastatic Breast Cancer

EAQ221CD Available Through ECOG-ACRIN Cancer Research Group

Improving Medication Adherence in Metastatic Breast Cancer Using a CONnected CUstomized Treatment Platform (CONCURxP)

Patient Population

See Section 3 for Complete Eligibility Details

Non-Patient Participants: Subset of oncology healthcare providers (n=~20) from a minimum of 10 participating NCORP affiliates and/or sub-affiliates

- Must have taken care of at least one patient randomized to Arm B who had less than 85% adherence rate at 12 months as measured by the WiseBag
- Must speak English; must be employed at an NCORP site for at least 6 months

Patient Eligibility– Step 0 (Screening Registration):

- ≥ 18 years old; must not have an ECOG PS ≥ 3 (or must not be deemed medically unable to participate)
- Must be fluent in written and spoken English **or** Spanish
- Must be present with new or established pathologically proven HR+ HER2– metastatic breast cancer
- Must have initiated any of the CKD4/6 inhibitors within 60 days prior to consenting to Step 0 or have received a prescription order with stated intent to initiate within 30 days following Step 0 consent
  - ◊ Must not have been previously treated with Palbociclib/Ibrance, Ribociclib/Kisqali, Abemaciclib/Verzenio
- Must not be enrolled in 1) a therapeutic clinical trial that monitors CDK4/6 inhibitors, or 2) a symptom science clinical trial that monitors/intervenes on symptoms related to CDK4/6i, or 3) other trials offering financial assistance
- Must have a personal mobile phone in which they are able and willing to send and receive text messages; must have an email address

Patient Eligibility– Step 1 (Randomization):

- Must have completed Baseline Survey and initiated their CDK4/6 inhibitors either 60 days prior to or 30 days after the date of OPEN screening registration (Step 0)
- Step 1 registration must occur within 45 days of Step 0 registration

Methodology Plan

See Section 5 for Methodology Details

- After consent/OPEN registration, NCORP CRA will:
  - ◊ Ask the patient to complete the Patient Contact Sheet
  - ◊ Encourage the patient to activate their EASEE-PRO account and complete the baseline survey
  - ◊ Enter patient contact info, incentive choice and method of delivery, and CRA contact data into UCI Redcap Project Enrollment Log
  - ◊ Complete subject randomization (after baseline survey); send info via Redcap to UCI/Emory
- **Baseline study procedures (both arms):**
  - ◊ Prescription schedule for CDK4/6 inhibitors and internal financial counseling documented in Redcap (by NCORP CRA)
  - ◊ Wise Bag activation (by UCI Coordinator)
  - ◊ Study package distribution (by UCI Coordinator)
  - ◊ Creation of patient's schedule on Wise pill portal (by UCI Coordinator)
- **Enhanced Usual Care (EUC)- Arm A:**
  - ◊ Use Wise Bag exclusively with prescribed CDK4/6i for ~ 12 months
  - ◊ Participants will receive a link every 4 weeks with educational materials (any patient-reported changes in their CDK4/6i prescription/schedule will be confirmed with the NCORP CRA)
- **CONCURxP Intervention- Arm B:**
  - ◊ Personalized and interactive bidirectional text messaging (smart reminders and missed dose questions specifically per drug); over-adherence confirmation/addressing; financial barrier addressing; patients able to view history of doses taken
- **See protocol for follow-up procedures for both arms (i.e., surveys at 3, 6, and 12 months)**

Study Chair:
Gelareh Sadigh, MD

Study Co-Chair:
Ilana Graetz, PhD

Patient Enrollment

All Sites: Oncology Patient Enrollment Network (OPEN) https://open.ctsu.org/open

Protocol Information

ECOG-ACRIN Operations-Boston: 857-504-2900, http://ecog-acrin.org (Member Login)

Please Enroll Your Eligible Patients!

EAQ221CD

ECOG-ACRIN cancer research group

A. Identify Site Population

Review patient lists, medical records, and/or HER reports to identify potentially eligible patients: ≥ 18 years old, having new or established HR+ HER2- metastatic breast cancer and a new prescription for CDK4/6i, who are not enrolled in any non-therapeutic trials offering financial assistance

B. Screen/Approach Patients

Site Staff:

Approach *all* potentially eligible patients (identified in **A** above):

- Verify (screen for) study eligibility
- Recruit eligible subjects for participation

C. Consent Patients

Site Staff:

Obtain written informed consent

D. Baseline Procedures

Site Staff:

Fax PC to OEAU

Encourage participant to either complete EASEE-PRO setup ASAP and complete baseline survey online or complete paper survey in the clinic

Submit a REDCap form with consented patient info

Email provider of patient's enrollment

Patients:

Complete baseline survey

E. OPEN Randomization (Step 1)

Site Staff:

Register patients to Step 1 in OPEN, upon completion of baseline survey

* Sample size in Step 1 = 390

Screen Log (REDCap survey hosted by UCI)

Site Staff: Enter a monthly summary into REDCap survey:

- Total number of eligible patients approached
- Total number of patients who refused to participate and reasons (optional)

OPEN Registration (Step 0)

Site Staff:

Register patients who sign consent into OPEN (Step 0)

Complete Registration to Study

Site Staff:

- Have the participant complete the Patient Contact sheet and fax it to the Brown OEAU (Tel: 855-404-3278 Fax: 401-863-9635)
- Encourage the patient to either activate their EASEE-PRO account and complete the baseline survey as soon as possible by logging into to the pride portal at https://pride.stat.brown.edu/Participant-Login (or by administering the baseline survey on paper in clinic) or complete paper surveys in the clinic and return to NCORP site staff/CRA
- Submit a REDCap form with consented patient information, choice of incentive and preferred method of receipt of incentive, and CRA contact
- Email participant's provider a notification of their patient's enrollment in the study

Obtain Randomization & WiseBag Setup

Site Staff:

- Register patients who complete baseline survey into OPEN (Step 1)
- Receive arm assignment

UCI Staff:

- Mail patients' incentives
- Mail WiseBag & Manual to participant
- Contact participant and assist with setup
- Create Wisepill schedule based on patient's treatment cycle and preferences

Arm A: Enhanced Usual Care

Emory: Text and email patients (monthly) educational materials and ensure patients' use of WiseBag

Arm B: CONCURxP

Emory: Monitor patient responses imbedded in intervention and refer to site staff when oncology referral or PAF referral needed

PAF: Document services offered to patient in REDCap

Site: Document results of oncology provider contact in REDCap

F. Follow-Up (3, 6, and 12 months)

EASEE-PRO/OEAU:

Send patient email notifications and reminders that post-intervention survey is able to complete or mail paper survey. Provide patient outreach to recover delinquent surveys. Send UCI notification when survey has been completed.

UCI:

Document and send appropriate incentives to patient for survey completion

Sites:

Review medical records

Update RAVE (vital status, treatment changes, pathology, etc.)

Document unexpected ED/hospitalization

Update REDCap (treatment, CDK4/6is changes, etc.)

NOTE: See protocol for the Non-Patient Participant Intervention Schema

G. Qualitative Interview (12 months Post-Randomization)

Emory:

Select and interview 30 patients and 20 providers from Arm B (CONCURxP)

* Site staff refers to NCORP site staff/CRA