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 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):**
- Must be ≥ 18 years of age; 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 30 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 previously been 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 within 30 days of OPEN screening registration (Step 0)

**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 as soon as possible (within 30 days)
  - 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)
  - WiseBag activation (by UCI Coordinator)
  - Study package distribution (by UCI Coordinator)
  - Creation of patient’s schedule on Wisepill portal (by UCI Coordinator)

- **Enhanced Usual Care (EUC) - Arm A:**
  - Use WiseBag 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

**Patient Enrollment**

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

**Protocol Information**

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

Please Enroll Your Eligible Patients!
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 CDK 4/6, 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 ESEE-PRO setup ASAP and complete baseline survey online or complete paper survey in the clinic
- Submit a REDCap form with consented patient information
- 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 = 300

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.)

G. Qualitative Interview (12 months Post-Randomization)
Emory:
Select and interview 30 patients and 20 providers from Arm B (CONCURxP)

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