Cancer Research Consortium of West Michigan
P: 616.391.1230 | 800.336.6299 | www.crcwm.org

FAST FACTS

EAQ221CD: Improving Medication Adherence in Metastatic Breast Cancer using a CONnected CUstomized Treatment Platform (CONCURxP)

ELIGIBILITY CRITERIA

Patient Eligibility Criteria for Step 0 (OPEN Screening Registration)

1 Patient must be ≥ 18 years of age.

2 Patient must be fluent in written and spoken English
OR Patient must be fluent in written and spoken Spanish

3 Patient must present with new or established breast cancer at the time of Step 0.

4 Patient must have initiated any of the CKD4/6 inhibitors (Palbociclib or Ibrance, Ribociclib or Kisqali, Abemaciclib or Verzenio) within 60 days prior to registration to Step 0 or have received a prescription order with stated intent to initiate within 30 days following registration to Step 0.

NOTE: Patients who have been treated previously with anticancer treatments other than CDK4/6 inhibitors are eligible.

NOTE: CDK4/6 inhibitors must be provided/supplied as a single agent blister pack. If the medication is supplied as capsules in a pill bottle (e.g., Ibrance capsules), patient is not eligible.

NOTE: Ribociclib (Kisgali) and Abemaciclib (Verzenio) are only available in blister packs. Palbociclib (Ibrance) is the only CDK4/6 inhibitor that might be available in a capsule formulation. However, this is an outdated formulation and is rarely

prescribed as a new start. The format of ordered Palbociclib can be determined based on the prescription order.

5 Patient must not have been previously treated with any of the following CDK4/6 inhibitors: Palbociclib or Ibrance, Ribociclib or Kisqali, and Abemaciclib or Verzenio.

6 Patient must not already be enrolled in a therapeutic clinical trial that monitors CDK4/6 inhibitors.

7 Patient must not be enrolled in a symptom science clinical trial that monitors or intervenes on symptoms related to CDK4/6 inhibitors.

NOTE: If NRG-CC012CD is activated in a participating practice, and a patient meets the eligibility criteria for both EAQ221CD and NRG-CC012CD, then EAQ221CD should be offered first to patients. Only if a patient is not eligible or not interested in participating in EAQ221CD, the NRG- CC012CD can be offered.

8 Patient must confirm that they intend to receive their care or monitoring at an NCORP site or one of the following two NCI- designated Comprehensive Cancer Centers: Emory University Winship Cancer Institute or University of California Irvine Chao Family Comprehensive Cancer Center.

9 Patient must have either a personal smartphone in which they agree to receive text messages.

or

an email in addition to a non-smart mobile phone in which they agree to receive text messages.

NOTE: Since mobile phones that are not smart phones cannot follow web links in a text message, people with non-smart mobile phones will also need an email address.

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 other trials offering financial assistance.

NOTE: Gift cards for survey completion, parking passes, or free medication provided as part of therapeutic trials are not considered financial assistance.

Patient Eligibility Criteria for Step 1 (OPEN Randomization)

1 Patient must meet all the eligibility criteria for Step 0 outlined in Section 3.2.1.

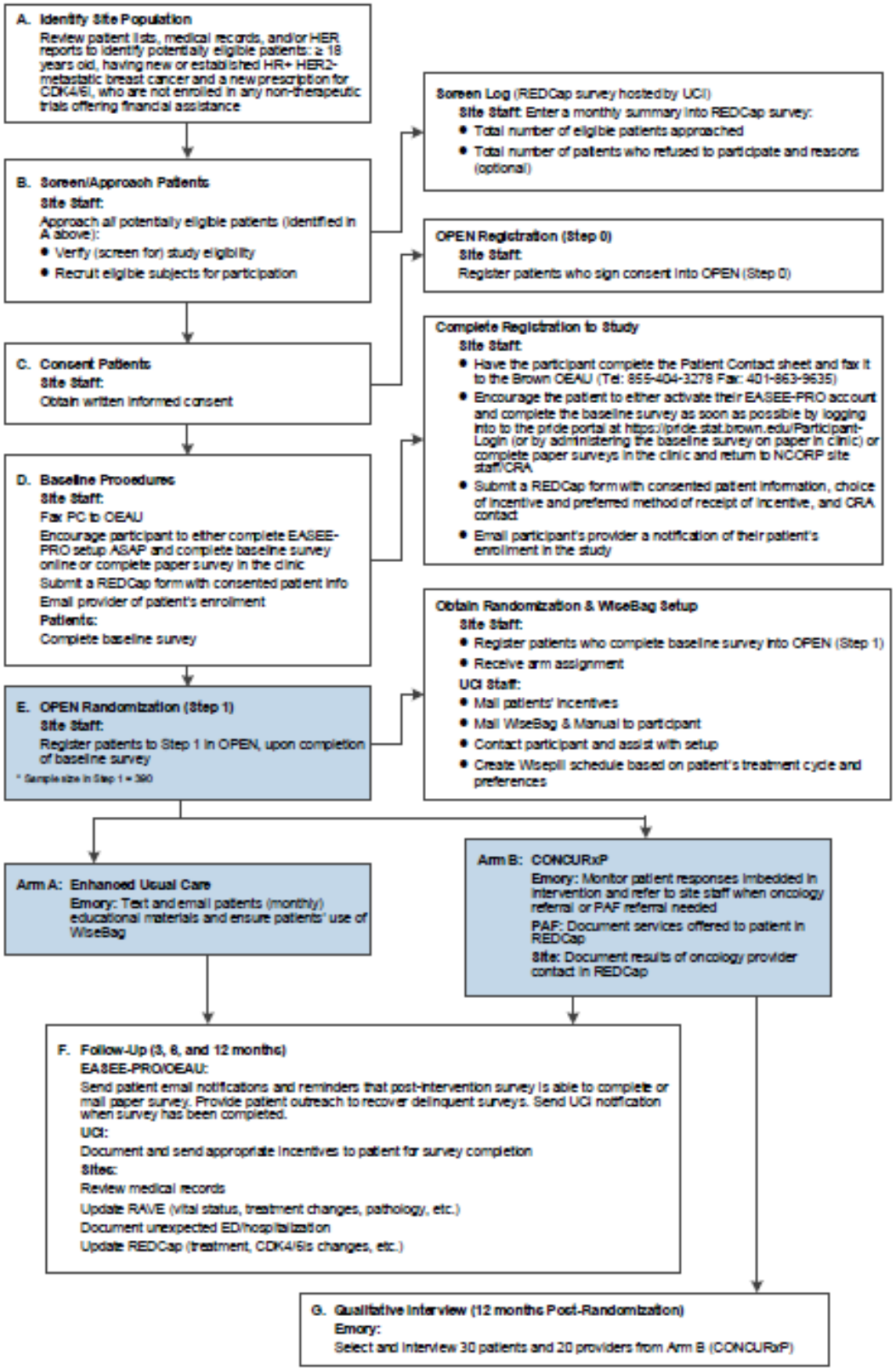
2 Patient must have signed a written informed consent form.

3 Patient must have completed Baseline Survey within 30 days after the date of OPEN Screening Registration (Step 0).

4 Patients must have initiated their CDK 4/6 inhibitors either 60 days prior to or 30 days after the date of OPEN Screening Registration (Step 0).

5 Step 1 registration must occur within 45 days of registration.

Patient Schema



* Site staff refers to NCORP site staff/CRA

Non-Patient Participant Intervention Schema