Cancer Research Consortium of West Michigan
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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 pathologically proven HR+ HER2- metastatic 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 consenting to Step 0 or have received a prescription order with stated intent to initiate within 30 days following Step 0 consent.

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 However, this is an outdated formulation and is rarely prescribed as a new start.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 Patients 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 Patients 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.

8 Patient must confirm that they intend to receive their care or monitoring at an NCORP site.

9 Patient must have a personal mobile phone in which they are able and willing to send and receive text messages.

NOTE: The restriction to those with mobile phone access with text messaging is based on the primary intention of the study which involves the use of text messaging to improve adherence.

10 Patient must have an email address.

NOTE: The restriction to those with an email address is based on the primary intention of the study which involves patients responding to questions regarding their reasons for non-adherence after every missed dose to improve adherence.

11 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.

12 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).

13 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.

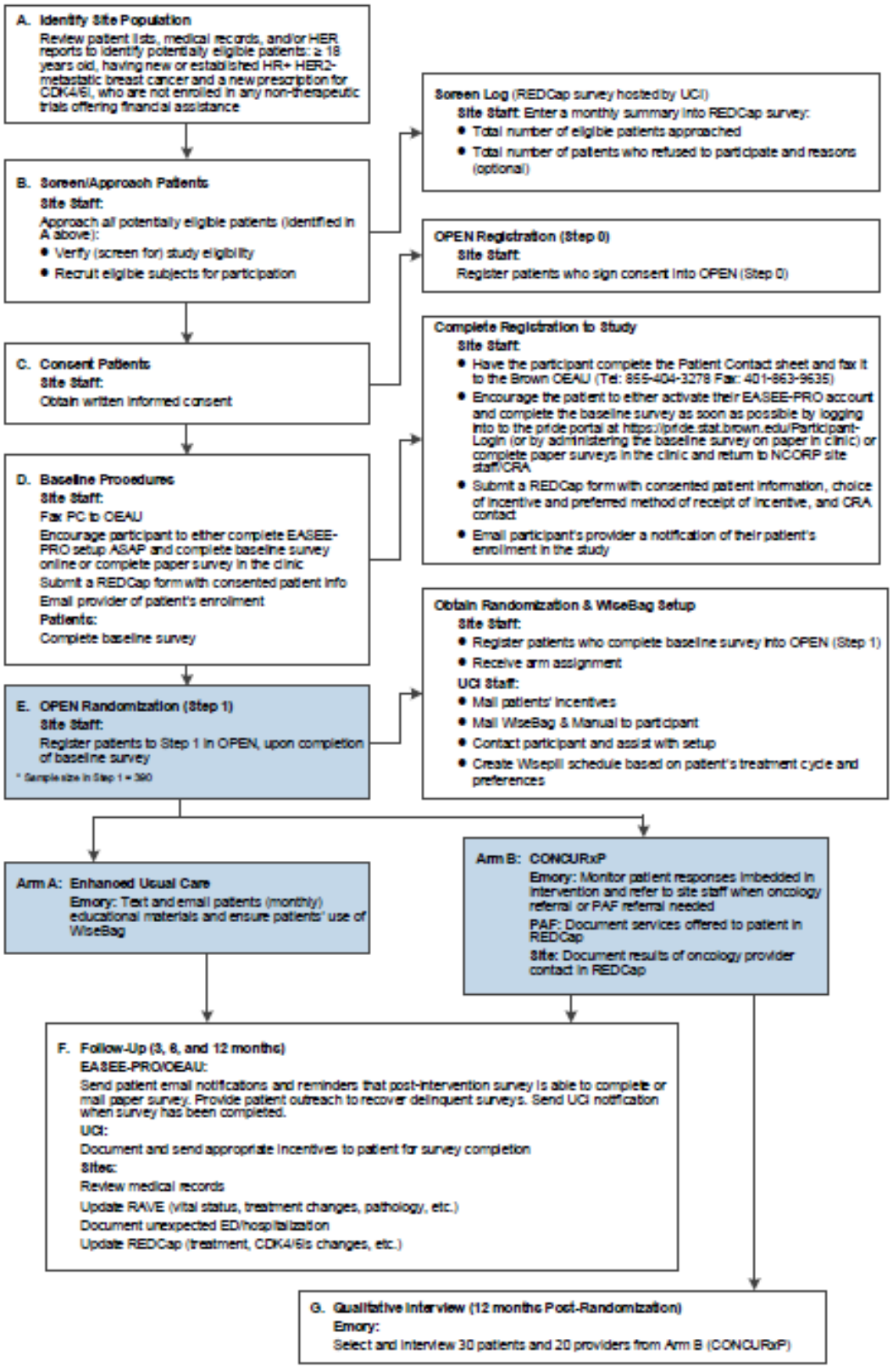
2 Patient must have signed a written informed consent form.

3 Patient must have completed Baseline Survey within 30 days of 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