

FAST FACTS

EAQ221CD: Improving Medication Adherence in Metastatic Breast Cancer using a CONNected CUsomized 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 CDK4/6 inhibitors (Palbociclib or Ibrance, Ribociclib or Kisqali, Abemaciclib or Verzenio) 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.

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 (Kisqali) 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 However, this is an outdated formulation and is rarely prescribed as a new start.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 confirm that they intend to receive their care or monitoring at an NCORP site.

8 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.

9 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.

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.

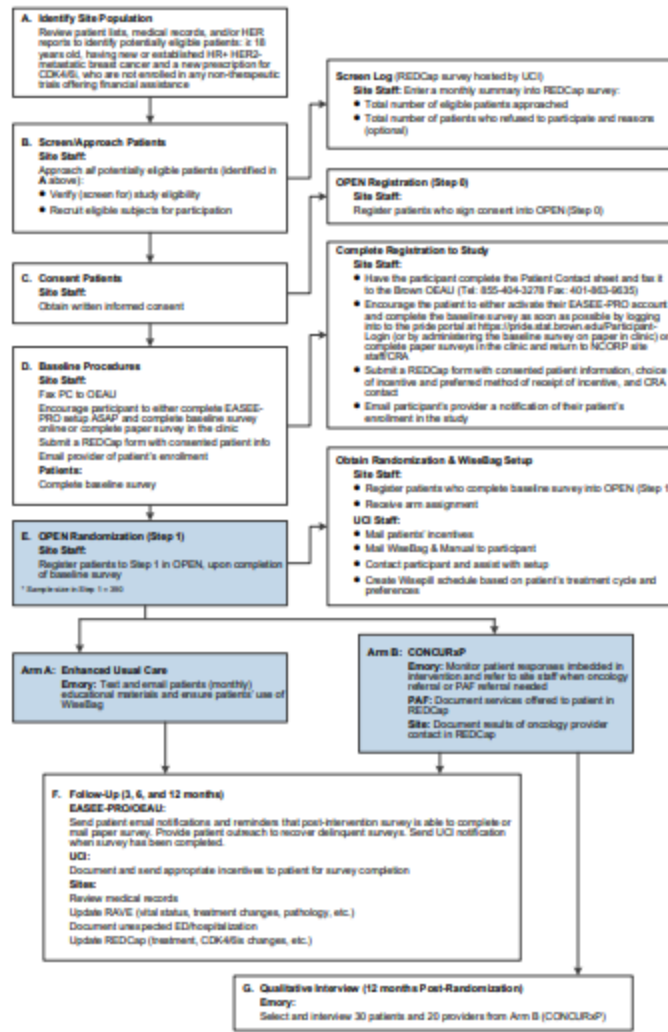
- 11 Patient must not have an ECOG Performance Status ≥ 3 . OR Patient must not be deemed medically unable to participate in the study by the study investigators or an oncology clinician (i.e., referral to hospice).
- 12 Patient must not be enrolled in other trials offering financial assistance.

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 of the date of Step 0 Registration.
- 4 Patients must have initiated their CDK 4/6 inhibitors within 30 days of the date of Step 0 Registration.

Patient Schema



* Site staff refers to NCORP site staff/CRA

Non-Patient Participant Intervention Schema

