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Use of clinical care registries to facilitate research study recruitment.

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The first and only CDK4 & 6 inhibitor approved in combination with fulvestrant and as a single agent for HR+, HER2- MBC¹

CDK4 & 6=cyclin-dependent kinases 4 and 6; HR+=hormone receptor positive; HER2=human epidermal growth factor receptor 2 negative; MBC=metastatic breast cancer.

INDICATION: Verzenio is indicated:

- In combination with fulvestrant for women with disease progression following endocrine therapy
- As a single agent for women with disease progression following endocrine therapy and who received 1 or 2 prior chemotherapy regimens in the metastatic setting

IMPORTANT SAFETY INFORMATION

Diarrhea occurred in 86% of patients receiving Verzenio plus fulvestrant in MONARCH 2 and 90% of patients receiving Verzenio alone in MONARCH 1. Grade 3 diarrhea occurred in 28% of patients receiving Verzenio plus fulvestrant in MONARCH 2.

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Use of clinical care registries to facilitate research study recruitment.

[Karen Messer](#), [Tracy M. Layton](#), [Tony Chen](#), [Viswanath Nandigam](#), [Katherine Abihider](#), [Peter W. Chase...](#)

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Abstract

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Background: We developed IRB-approved secure research registries for our Breast Imaging and Breast Care Clinics at Moores UC San Diego Cancer Center, as part of the UC statewide Athena Breast Health Network. Our clinical care registries securely store patient-reported intake data, which are summarized and uploaded into the medical record for patient care. Following consent, data are securely maintained in a separate research registry. In addition to facilitating quality assurance data collection, these registries aim to 1) maintain a data-rich research registry, 2) offer patients research opportunities, and 3) facilitate participant screening and recruitment into research studies. **Methods:** Breast Imaging or Breast Care clinic patients complete an online clinical intake form prior to their appointment, either at home or using an iPad in clinic, and are given the opportunity to be involved in research. Patients are asked for site-specific consent to keep personally identifiable intake data in a research registry, for consent to be approached about providing a biospecimen sample, and for consent to be contacted for future research opportunities. Data from consented participants are pulled into secure databases available to study personnel. **Results:** Participants to date include 4,480 patients, of whom 3,246 consented to use of data for research (72%), and 2,627 have agreed to be contacted for future research opportunities (59%). In a pilot biospecimen collection protocol, 46% of patients agreed to be approached and we have collected over 360 blood or saliva and 51 tissue samples. Additionally, with the use of future contact consent, we have facilitated recruitment of more than 370 participants to multiple lifestyle and survey-based clinical studies. **Conclusions:** Patients are willing to participate in research, especially in a research registry that requires little additional time on their part. The use of

COMPANION ARTICLES

No companion articles

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The first and only CDK4 & 6 inhibitor approved in combination with fulvestrant and as a single agent for HR+, HER2- MBC¹

CDK4 & 6=cyclin-dependent kinases 4 and 6; HR+=hormone receptor positive; HER2=human epidermal growth factor receptor 2 negative; MBC=metastatic breast cancer.

INDICATION: Verzenio is indicated:

- In combination with fulvestrant for women with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) metastatic breast cancer (MBC) in MONARCH 2.

Instruct patients that at the first sign of loose stools, they should start antidiarrheal therapy such as loperamide, increase oral fluids

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research registries allows collection of a variety of data elements useful for prescreening participants for research studies, including body mass index, age, menopausal status and breast cancer diagnosis. Data- and participant-rich research registries facilitate efficient screening and recruitment for other research studies.

[Ontario and American Society of Clinical Oncology Clinical Practice Guideline](#)

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