Do you have metastatic breast cancer with bone or mostly bone disease and beginning a new treatment soon?

Are you interested in helping researchers determine if FDG-PET/CT provides a better assessment of how metastatic breast cancer is responding to treatment than standard of care imaging?

Ask your doctor about EA1183/FEATURE.

If you would like to know more about the EA1183/FEATURE study:

- Ask your doctor
- Visit www.ecog-acrin.org and search EA1183, then select the link to EA1183. If you are seeking information about medical facilities where this trial is available, scroll down the page to Locations and Contacts
- Call the NCI Cancer Information Service at 1-800-4-CANCER (1-800-422-6237)

About clinical trials and general cancer information:

- General cancer information: visit the NCI website at www.cancer.gov
- Insurance coverage: visit www.cancer.gov/clinicaltrials/learningabout/payingfor

About the ECOG-ACRIN Cancer Research Group:

- Visit www.ecog-acrin.org

Please contact:

Name

Phone

EA1183/FEATURE Study

Using FDG-PET/CT to Assess Response of Bone-dominant Metastatic Breast Cancer
**Why is this study being done?**

- The usual approach for patients with metastatic breast cancer that is in the bone, or mostly in the bone, is to take a picture of their tumor(s) with a bone scan or a CT scan of the bones.
- EA1183/FEATURE aims to find out if FDG-PET/CT imaging is better than the usual approach.
- Positive findings of EA1183/FEATURE will secure the role of FDG-PET/CT as a response measure for patients with bone only or mostly bone disease, and allow for inclusion of this patient population in multicenter clinical trials where response is an endpoint. Accurate response criteria will permit discontinuation of ineffective therapies at an earlier time point, which may result in less toxicity and improved outcomes for patients who switch to more effective therapies.

**You may be able to join this study if:**

- You have been diagnosed with metastatic breast cancer with bone or mostly bone disease (confirmed by scans within 60 days of study registration).
- Your plan with your doctor is to receive 1st, 2nd, or 3rd line endocrine therapy for metastatic breast cancer, chemotherapy, or HER2-targeted therapy.
- You have had no more than three cytotoxic chemotherapies.
- You have no contraindication to undergoing FDG-PET imaging.

### If you decide to participate in this study:

- You will have a FDG-PET/CT scan prior to beginning new treatment for your breast cancer.
  - If you have recently had a FDG-PET/CT scan, your doctor will let you know if that FDG-PET/CT can be used for the study.
- You will then have a second FDG-PET/CT scan approximately 12 weeks after starting treatment.
- After you finish the 12 week FDG-PET/CT scan, your doctor and study team will continue to monitor you with exams, labs and imaging, which may include standard of care CT, bone scan, MRI, or FDG-PET/CT.
  - These evaluations will occur every 3 months for 1 year and then every 6 months for as long as needed, based on the response of the breast cancer to treatment and your symptoms.
- Please note, you can decide to stop participating in EA1183/FEATURE at any time (even after you have enrolled). Otherwise, your participation in this study will be 3–5 years total.

### What are the costs of taking part in this study?

- You and/or your insurance provider will need to pay for the costs of medical care you get as part of the study, just as you would if you were getting the usual care for metastatic breast cancer.
- You and/or your insurance provider will not have to pay for exams, tests, and procedures done for research purposes only or that are covered by the study. This includes the two study FDG-PET/CT scans, the optional blood draws, and the optional FDG-PET/CT scan.
  - Note: If you have a FDG-PET/CT scan completed prior to joining this study that can be used, this scan may have already been billed to your insurance and is not reimbursed.

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**You agree to take part in the study and sign the consent form**

- Complete a FDG-PET/CT prior to undergoing new therapy for breast cancer
- Begin initial or new therapy (physician choice) within 21 days of FDG-PET/CT scan
- Complete second FDG-PET/CT scan 12 weeks after starting therapy

**Follow-up**