Accrual goal = 1450 patients.
Suspicious lesions detected on 1 or both modalities at year 0 or 1 time points will be biopsied as per local standard practice.
Tissue collection and analysis for all cancers detected.
Patients will undergo both DBT and AB-MR within 30 days following randomization. DBT and AB-MR will be performed on the same date and interpreted by 2 different radiologists, each blinded to the other modality. Sites may perform DBT and AB-MR within 24 hours of each other, but same-day testing is optimal, if radiologists remain blinded to results of the other modality.
Patients will be randomized to the order of which study is performed first.
All women will undergo DBT and AB-MR at 1 year in the same order as baseline DBT and AB-MR.
*Year 0 PRO/QOL assessments to be completed approximately 2 weeks after screenings.
AB-MR = abbreviated breast MRI; DBT = digital breast tomosynthesis; PRO = patient-reported outcomes; QOL = quality of life.
Study Objectives

Primary Objective
- Compare the rates of detection of invasive cancers between AB-MR and DBT

Secondary Objectives
- Compare the positive predictive value (PPV) of biopsies, call-back rates, and short-term follow-up rates after AB-MR and DBT on initial and 1-year follow-up studies
- Estimate and compare the sensitivity and specificity of AB-MR and DBT, using the 1-year follow-up to define a reference standard
- Compare patient-reported short-term quality of life related to diagnostic testing with AB-MR and DBT using the Testing Morbidities Index
- Compare the willingness to return for testing with AB-MR versus DBT within the recommended screening interval, and explore factors associated with willingness to return for screening
- Compare the tumor biologies of invasive cancers and ductal carcinoma in situ (DCIS) detected on AB-MR and DBT
- Estimate the incident cancer rate during 3 years following the year 1 AB-MR/DBT when patients return to standard screening

Overall EA1141 Study Objective
To compare the effectiveness of abbreviated breast MRI (AB-MR) to digital breast tomosynthesis (DBT) and examine the value of a low-cost AB-MR protocol as a supplemental screening method to mammographic screening in women with dense breasts
Eligibility Criteria*

Main Inclusion Criteria
- Women ages 40 to 75 years and scheduled for routine screening DBT
- Breast density must be known; patients must have mammographically dense breasts (ACR breast density category c or d [heterogeneous or extreme fibroglandular tissue]) on their most recent prior screening
- Asymptomatic for breast disease and undergoing routine screening
- Agree to not undergo screening ultrasound (of breast) for the duration of the 1-year study period, as it adds no benefit to women undergoing breast MRI
- Able to undergo breast MRI with contrast enhancement
- Use of effective contraception or abstinence

Main Exclusion Criteria
- Known breast cancer (DCIS or invasive cancer), currently undergoing treatment for breast cancer, or planning surgery for a high-risk lesion (atypical ductal hyperplasia, atypical lobular hyperplasia, lobular carcinoma in situ, papilloma, radial scar)
- Taking chemoprevention for breast cancer
- Undergone screening breast ultrasound within 12 months prior to randomization
- Previously had molecular breast imaging (MBI, MIBI)
- Suspected of being at high risk for breast cancer, as defined by the ACS breast MR screening recommendations (lifetime risk of ≥ 20%-25%)
- Previously had a breast MRI

*When evaluating patients for this study, please refer to the full protocol for the complete list of eligibility criteria.
Main Exclusion Criteria (cont)

- History of untreatable claustrophobia, sickle cell disease, contraindication to intravenous contrast administration, or known allergy-like reaction to gadolinium or moderate or severe allergic reactions to one or more allergens as defined by the ACR
- Presence of non-MR-compatible metallic objects or metallic objects that (in radiologist’s opinion) would make MRI a contraindication
- Known or suspected renal impairment
- Weight higher than that allowable by the MRI table
- Prior contrast-enhanced mammography (spectral [CESM] or digital [CEDM])
- Breast prosthetic implants (silicone or saline)
- Pregnancy or breast-feeding