Comparison of Abbreviated Breast MRI and Digital Breast Tomosynthesis in Breast Cancer Screening in Women With Dense Breasts

**Overall Study Goal**
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.

**Study Schema**
Women ages 40-75 with dense breasts already scheduled for routine screening DBT

<table>
<thead>
<tr>
<th>RANDOMIZE</th>
<th>Arm A* (DBT First)</th>
<th>Years 0 and 1 DBT followed by AB-MR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arm B* (AB-MR First)</td>
<td>Years 0 and 1 AB-MR followed by DBT</td>
<td></td>
</tr>
</tbody>
</table>

Return to routine mammographic screening and follow for 3 years

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.

**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 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.
How Your Site Can Participate

• **Before recruitment**, investigators must be registered members of an NCTN network group.

• Investigators must have an NCI investigator number and maintain “active” registration status by annually submitting a registration packet (current CV and signed FDA Form 1572, Supplemental Investigator Data Form, and Financial Disclosure Form) to the FDA and NCI. Please refer to the Cancer Therapy Evaluation Program (CTEP) Web site for information and forms

• Sites participating on the NCI CIRB initiative and approved by the CIRB for this study need not submit separate IRB approval documentation to the CTSU. For these sites, IRB data automatically load to RSS. Signatory institutions must submit a Study Specific Worksheet for Local Context (SSW) to the CIRB via the IRBManager to indicate intent to open the study locally. The CIRB’s approval of SSW is then communicated to the CTSU Regulatory Office. For SSW approval to be processed, the signatory institution must inform the CTSU of which CIRB-approved institutions aligned with the signatory institution are participating in the study.

• **Requirements for EA1141 site registration:**
  - CTSU Transmittal Sheet (optional)
  - IRB approval (for sites not participating via the NCI CIRB; local IRB documentation, IRB-signed CTSU IRB Certification Form, Protocol of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption Form, or combination is accepted)
  - MRI Qualification (through ACR Imaging Core Laboratory)
    • ACR breast MRI accreditation
    • AB-MR reader training certification

• **Submit all required regulatory documents to:**
  - CTSU Regulatory Office
    1818 Market Street, Suite 1100
    Philadelphia, PA 19103
    Fax: (215) 569-0206
    E-mail: CTSURegulatory@ctsu.coccg.org
    Online: [www.ctsu.org](http://www.ctsu.org) (members’ section) → Regulatory Tab → Regulatory Submission
  - Institutions with patients waiting and unable to use the portal should alert CTSU Regulatory Office immediately at 866-651-2878

• **Required regulatory documentation:**
  - Copy of IRB Informed Consent Document
  - CTSU IRB Certification form or Signed HHS OMB No. 0990-0263 (replaced Form 310) or IRB Approval Letter
  
  **Note:** Submission must include all sites approved for the protocol under an assurance number; OHRP assurance number of reviewing IRB; OHRP IRB Registration Number of reviewing IRB; full protocol title and number; version date; type of review (full board vs expedited); date of review; signature of IRB official.

• Check registration status at [https://www.ctsu.org](https://www.ctsu.org)

• **Once documentation has been submitted and approved:**
  - Patients must not start protocol trial procedures before randomization; imaging starts within 30 working days after randomization
  - Patient enrollment is via OPEN, accessed at [https://open.ctsu.org](https://open.ctsu.org). Data collection is exclusively through Medidata Rave. Address OPEN and Medidata Rave questions to the CTSU Help Desk at 1-888-823-5923 or [ctsucontact@westat.com](mailto:ctsucontact@westat.com)
  - Biologic specimens must be submitted per protocol Section 10
  - Patient Reported Outcomes (PROs) must be reported using the ECOG-ACRIN Systems for Easy Entry of Patient Reported Outcomes (EASEE-PRO). See protocol Section 8.2
  - TRIAD will be the sole method of imaging data transfer to the ACR Clinical Research Center Core Laboratory. For questions on TRIAD image submission, contact 703-390-9858 or [TRIAD-Support@acr.org](mailto:TRIAD-Support@acr.org).

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**Contact Information**

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**For Further Study Information**

- For more information about the EA1141 study, please visit the following:
  - Clinicaltrials.gov; search NCT02933489
- For more information about ECOG-ACRIN, visit [ecog-acrin.org](http://ecog-acrin.org)