ACR, BCRF and GE HealthCare Announce Enrollment of First Patients in Contrast Enhanced Mammography Imaging Screening Trial (CMIST)

Study aims to determine whether CEM improves breast cancer detection for women with dense breasts

The American College of Radiology (ACR), Breast Cancer Research Foundation (BCRF) and GE HealthCare announce the enrollment of the first patients in the Contrast-Enhanced Mammography Imaging Screening Trial (CMIST). This is a significant milestone for the clinical trial that will help determine whether contrast-enhanced mammography (CEM) improves breast cancer detection and reduces false-positive exams in women with dense breasts.

Breast cancer is currently the most commonly diagnosed cancer among American women – with about one in eight facing a diagnosis in their lifetime.[1] While mammography is considered the standard breast cancer screening tool, its effectiveness is reduced in women with dense breast tissue.[2] Dense breast tissue is a lesser-known risk factor that can double one's risk for breast cancer[3] and will soon require patient notification in the United States as a result of updates to the Mammography Quality Standards Act (MQSA) announced by the U.S. Food and Drug Administration. While dense breast tissue is considered common, with about 40 percent of women aged 40 and older having dense breasts,[4] it can make the detection of breast cancer more challenging. For some patients, tissues can overlap potentially hiding signs of breast cancer; in other cases, the tissue and cancer can show up as white on a mammogram making diagnosis more difficult. As a result, patients often need to seek supplementary screening.

CEM combines mammography and iodinated contrast media in a simple and quick procedure to highlight areas of unusual blood flow patterns that may indicate malignancy. The CMIST study seeks to determine if CEM provides more accurate cancer detection compared to digital breast tomosynthesis (DBT), or 3D mammography, in women with dense breasts. As part of CMIST, a total of 2032 women with dense breasts will be enrolled to compare the CEM technique to 3D mammography.

Carolina Breast Imaging Specialists (CBIS) in Greenville, North Carolina is the first of fifteen planned sites to start recruiting patients, with additional sites across the United States and Canada commencing recruitment in the coming months. The trial is set to deliver the first results in 2025. The trial is registered on ClinicalTrials.gov under NCT05625659.

"We are very proud and excited to have enrolled the first patients in the multi-center CMIST trial," said Dr. Bruce Schroeder – Medical Director and CEO of Carolina Breast Imaging Specialists. "Our patients have been eager to participate in this landmark trial both for its potential to find the earliest cancers and for its role in providing much needed data to our global knowledge base. We expect this long-awaited study to show us the value of finally having a highly effective, low-cost examination for women with dense breasts and other challenging circumstances."

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[1] Breastcancer.org. Breast Cancer Facts and Statistics. Available at: https://www.breastcancer.org/facts-statistics. Last accessed March 2023.
[2] Buchberger W, Geiger-Gritsch S, Knapp R, Gautsch K, Oberaigner W. Combined screening with mammography and ultrasound in a population-based screening program. Eur J Radiol. 2018 Apr;101:24-29
[3] Nelson HD, Zakher B, Cantor A, et al. Risk factors for breast cancer for women aged 40 to 49 years: a systematic review and meta-analysis. Ann Intern Med. 2012;156(9):635-648.
[4] Pisano et al. NEJM 2005; 353: 1773.

“Dense breast tissue is not only a risk factor, but also makes it increasingly difficult to identify breast cancer. The FDA’s recent announcement requiring a single national “dense breast” reporting standard after years of advocacy is a win for patients, as well as providers, in the fight against breast cancer,” said Jyoti Gupta, PhD – President & CEO for Women’s Health and X-ray at GE HealthCare. “Providing women with this information offers the potential for early diagnosis and empowers women with dense breasts to make informed and personalized decisions about their breast health through supplemental imaging, like contrast-enhanced mammography. I’m excited to see our Senographe Pristina mammography system, SenoBright HD CEM technology and contrast media from our Pharmaceutical Diagnostics segment being used to further evaluate the clinical benefits of CEM as part of our efforts to improve breast cancer outcomes.”

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About the American College of Radiology

The American College of Radiology (ACR), founded in 1924, is a professional medical society dedicated to serving patients and society by empowering radiology professionals to advance the practice, science and professions of radiological care. acr.org

About BCRF

Breast cancer is a complex disease with no simple solution. Research is the key to stopping it in its tracks. Founded in 1993 by Evelyn H. Lauder, BCRF is the largest private funder of breast cancer research in the world. Investing in the best minds in science—from those investigating prevention, diagnosis, treatment, survivorship, and metastasis—and foster cross-disciplinary collaboration, BCRF's approach accelerates the entire field and moves us closer to the answers we urgently need to be the end of breast cancer. Learn more and get involved at BCRF.org.

About GE HealthCare Technologies Inc.

GE HealthCare is a leading global medical technology, pharmaceutical diagnostics, and digital solutions innovator, dedicated to providing integrated solutions, services, and data analytics to make hospitals more efficient, clinicians more effective, therapies more precise, and patients healthier and happier. Serving patients and providers for more than 100 years, GE HealthCare is advancing personalized, connected, and compassionate care, while simplifying the patient’s journey across the care pathway. Together our Imaging, Ultrasound, Patient Care Solutions, and Pharmaceutical Diagnostics businesses help improve patient care from diagnosis, to therapy, to monitoring. We are an $18.3 billion business with 50,000 employees working to create a world where healthcare has no limits.