

Recommendations of the ACR Data Safety Monitoring Board July 26, 2023

The ACR Data Safety Monitoring Board (DSMB) met via webinar on July 26, 2023, to review the following protocols: ACRIN 4703 (DECAMP-1), ACRIN 4704 (DECAMP-2), and ACR 4707 (CMIST).

This report is being provided to study investigators for transmission to participating sites' local IRBs.

The protocol team's statistician prepares a study data report for the DSMB, which includes aggregated and summarized adverse event data. The DSMB report and review include an examination of adverse events, consideration of whether studies were making adequate progress towards completion, and, when appropriate, examination of interim outcome results. Results from other studies and other recent literature that might be relevant to the research were also considered.

The ACR DSMB charter is available upon request by contacting Irene Mahon at imahon@acr.org.

The ACR DSMB recommendations for the studies reviewed on July 26, 2023 are listed below:

<p>ACRIN 4703 DECAMP-1: Diagnosis and Surveillance of Indeterminate Pulmonary Nodules <i>Study Chairs: Ehab Billatos, MD and Denise Aberle, MD</i> <i>Statisticians: Constantine Gatsonis, PhD and Fenghai Duan, PhD</i></p> <p>Recommendation: Continue to follow-up per protocol.</p>
<p>ACRIN 4704 DECAMP 2: Screening of Patients with Early Stage Lung Cancer or at High Risk for Developing Lung Cancer <i>Study Chairs: Ehab Billatos, MD and Denise Aberle, MD</i> <i>Statisticians: Constantine Gatsonis, PhD and Fenghai Duan, PhD</i></p> <p>Recommendation: Continue to follow-up per protocol</p>
<p>ACR 4707: Comparison of Breast Cancer Screening with Dual-Energy Contrast-Enhanced Spectral Mammography to Digital Breast Tomosynthesis in Women with Dense Breasts (Contrast Mammography Imaging Screening Trial – CMIST) <i>Study Chair: Christopher Comstock, MD</i> <i>Statistician: Laura Gillis, PhD</i></p> <p>Recommendation: Continue per protocol</p>

The next ACR DSMB meeting will be scheduled (date to be determined) in January 2024.