

Recommendations of the ACR Data Safety Monitoring Board

January 17, 2023

The ACR Data Safety Monitoring Board (DSMB) met via webinar on January 17, 2023, to review ACRIN 4703/DECAMP-1 and ACRIN 4704/DECAMP-2. This report is being provided to the DECAMP investigators for transmission to participating sites' local IRBs.

The Brown University Center for Statistical Sciences 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 DECAMP DSMB charter is available upon request by contacting Irene Mahon at: imahon@acr.org

The DSMB recommendations for the DECAMP studies are listed below.

ACRIN 4703 | DECAMP 1: Diagnosis and Surveillance of Indeterminate Pulmonary Nodules

Study Chairs: Ehab Billatos, MD and Denise Aberle, MD

Statisticians: Constantine Gatsonis, PhD and Fenghai Duan, PhD

Recommendation:

- Continue to follow-up per protocol.

ACRIN 4704 | DECAMP 2: Screening of Patients with Early Stage Lung Cancer or at High Risk for Developing Lung Cancer

Study Chair: Ehab Billatos, MD and Denise Aberle, MD

Statisticians: Constantine Gatsonis, PhD and Fenghai Duan, PhD

Recommendation:

- Continue per protocol
- Confirm that all sites have local IRB approval of Amendment 11 (which acknowledges closure to accrual as of 12/30/2022).

The next DSMB review of the DECAMP studies will be scheduled (date to be determined) in July 2023.