

Recommendations of the ACR Data Safety Monitoring Board

January 26, 2022

The ACR Data Safety Monitoring Board (DSMB) met via webinar on January 26, 2022 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 ACRIN Biostatistics and Data Management Center 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 Jessica Howell at jhowell@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

Recommendations:

- Continue 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:

- The ACR DSMB committee approved a proposed amendment that would halt accrual to the trial in December of 2022.
- Until proposed amendment is complete, all sites are to continue per protocol.

The next DSMB review of the DECAMP studies is scheduled for July 19, 2022.