

Recommendations of the ACRIN PA Data Safety Monitoring Board, January 4, 2017

The ACRIN PA Data Safety Monitoring Board (DSMB) met via webinar on January 4, 2017 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 included 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 Chair: Dr. Avrum Spira

Statisticians: Constantine Gatsonis and Fenghai Duan

- Protocol team should revise the sample size and sample size estimates. Update the protocol to reflect an accurate prevalence cancer rate and if the effect size is smaller it will justify the sample size.
- **Recommendation:** 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: Dr. Avrum Spira

Statisticians: Constantine Gatsonis and Fenghai Duan

- Reported AE's are lower than anticipated. Protocol team to clarify definition and instructions for reporting AE's.
- **Recommendation:** Continue per protocol.

The next DSMB review of the DECAMP studies is scheduled for July 19, 2017.