

Recommendations of the ACRIN PA Data Safety Monitoring Board, January 22, 2018

The ACRIN PA Data Safety Monitoring Board (DSMB) met via webinar on January 22, 2018 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

- **Recommendation:** Continue per protocol.
- Implement strategies to meet or exceed the self-imposed goal of enrolling 80-100 subjects per year:
 - Identify 'best practices' at sites that are meeting enrollment goals.
 - Analyze screening log data
 - Implement incentives for physicians and patients
 - Hold an investigator meeting to discuss recruitment strategies and accrual goals, and 'best practices'

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

- **Recommendation:** Continue per protocol.
- Implement strategies to increase enrollment (as suggested for DECAMP 1 above).

The next DSMB review of the DECAMP studies will be scheduled in July 2018.