Winter 2021

TSOG NEWS

AATS Thoracic Surgery Oncology Group

A joint venture between AATS and Memorial Sloan Kettering

In This Issue

Chair's Report

David R. Jones, MD

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On behalf of the TSOG Executive Committee, we hope you and your families are well during this COVID crisis. Although these are unusual times for us all, TSOG continues to push the envelope and remain relevant. At one point since our last newsletter, sites with open TSOG trials had doubled within a 3-month time frame. This is in part due to the TSOG Site Coordinator Working Group, which is composed of our site coordinators.

TSOG has expanded to include twenty-seven sites in total, welcoming new sites Mayo Clinic–Jacksonville, PI Ian Makey; University of Pennsylvania, PI Doraid Jarrar; and Vanderbilt University, PI Erin Gillaspie. In ensuring the data and regulatory quality of our trials, Memorial Sloan Kettering Cancer Center and MD Anderson have begun auditing our respective site-initiated trials.

In this newsletter, we share updates on the current TSOG trials and two upcoming trials, describe the ongoing audits of TSOG projects, touch on the Site Coordinator Working Group, and highlight Laura Carpenter, RN, from Washington University for her hard work and contributions to TSOG.

We would like to thank all TSOG member PIs and site coordinators for your efforts in activating and accruing to TSOG trials. Let us keep the momentum going in 2022 and strive for even more success!

Update on Current TSOG Trials

Since August 2020, both the number of TSOG sites open to accrual and the number of patients accrued have multiplied for the majority of our trials.

James M. Isbell, MD, MSCI

TSOG 101 – "Evaluation of perioperative circulating tumor DNA analysis as a prognostic biomarker in patients undergoing neoadjuvant therapy for resectable non-small cell lung cancer," led by Dr. James Isbell from Memorial Sloan Kettering Cancer Center, is open to accrual at 13 sites, with hopes of operating at 16 sites by the end of 2022. There are 57 patients on study across all sites. Most recently, TSOG 101 opened to accrual at the University of Montreal (study PI Moishe Liberman, MD), Duke University (study PI Betty Tong, MD), and Rush University (study PI Christopher Seder, MD). Since the study's activation in June 2021, the University of Montreal has accrued 11 patients, making it the second highest accruing site.

James Huang, MD

TSOG 102 – "Registry trial for the active surveillance for multifocal ground glass opacities (GGOs)," led by Dr. James Huang from Memorial Sloan Kettering Cancer Center, has also multiplied in size with site activations and accrual. The study is currently open at 18 TSOG sites and has accrued over 180 patients. The most recent activations were at Thomas Jefferson University (study PI Nathaniel Evans, MD), University of Pittsburgh (study PI Arjun Pennathur, MD), and Roswell Park (study PI Todd Demmy, MD). Championed by study PI Douglas Liou, Stanford University is the second highest accruing TSOG site for this trial with 21 patients on study since its activation in May 2021. With the current rate of patient enrollment across TSOG sites, TSOG 102 is expected to close to accrual in 18 to 24 months.

Mara Antonoff, MD

TSOG 103 - Led by Dr. Mara Antonoff from MD Anderson Cancer Center "The role of multimodality management in risk-stratified patients with lung-limited metastatic colorectal cancer" also continues to expand, with activations at Thomas Jefferson University (study PI Nathaniel Evans, MD) and Memorial Sloan Kettering Cancer Center (study PI Bernard Park, MD). The trial was closed secondary to poor accrual at Washington University in June 2021. However, TSOG 103 is expected to be open to accrual at six sites by the end of 2022. The trial currently has 30 patients on study across all sites.

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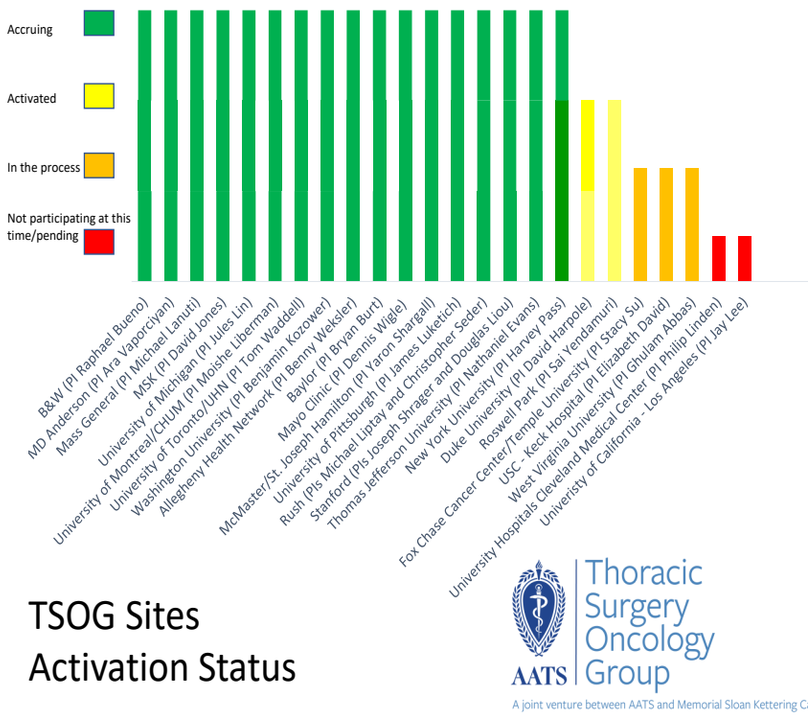
Harvey Pass, MD

TSOG 104 – "Validation of fibulin 3 as a biomarker for pleural mesothelioma," led by Dr. Harvey Pass of NYU Langone Medical Center, is supported by a grant to Dr. Pass from the NCI Early Detection Research Network (EDRN). The EDRN is an initiative of the NCI that brings together institutions to help accelerate the translation of biomarker information into clinical applications and to evaluate new ways of testing cancer in its earliest stages and for cancer risk. Dr. Pass has identified TSOG sites to participate in the EDRN sponsored trial. This trial was previously presented during the TSOG Semi-Annual Meeting in February 2020. The aims of the study are to prospectively collect pleural effusions from newly diagnosed or treated patients with pleural effusions; measure FBLN3 levels in deidentified, blinded, prospectively collected specimens using the mab428.2 ELISA. The trial is currently open at NYU where the correlative studies will be performed in the Thoracic Surgery Laboratory. TSOG 104 is expected to be activated at the University of Toronto/University Health Network, Baylor College of Medicine, Brigham and Women's Hospital, Memorial Sloan Kettering Cancer Center, and Duke University.

TSOG Sites Open to Accrual

Update December 2021	TSOG 101 ctDNA Trial	TSOG 102 GGO Trial	TSOG 103 Colorectal Mets Trial	TSOG 104 Mesothelioma Trial
On Study	57 48% complete	179 54% complete	30 8% complete	99
Sites Open	13	18	5	1
Target Accrual	120	330	300	250
Sites Accruing	11 14 sites–no accrual	16 9 sites–no accrual	3	1
Highest Accruing Sites 2021	MSK	MSK	MD Anderson	NYU
Second Highest Accruing Sites 2021	University of Montreal	Stanford University	University of Toronto and Thomas Jefferson University	Awaiting site initiation visit



TSOG Sites
Activation Status

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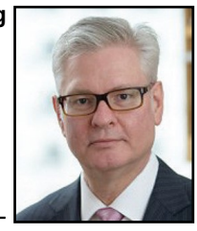
TSOG Proposal Updates

LCMC4 Evaluation of Actionable Drivers in EaRly stage lung cancer (LEADER trial)


David R. Jones, MD

TSOG PI: David R. Jones, MD

Memorial Sloan Kettering Cancer Center

This proposal was previously presented during TSOG's Semi-Annual Meeting in February 2020. This collaborative screening protocol, developed by the Lung Cancer Mutation Consortium, managed by the Lung Cancer Research Foundation, and supported by TSOG, is designed to determine the feasibility of comprehensive molecular profiling to detect actionable oncogenic drivers in 1000 patients with suspected early-stage lung cancers scheduled to undergo biopsies to establish the diagnosis of lung cancer. Patients with an identified targetable alteration will be offered enrollment in a neoadjuvant clinical trial. Correlative endpoints for this study will include tumor and ctDNA genomics, clinicopathologic variables, and outcomes. Data on screen fails (estimated to be 70% of the cohort) will be available to TSOG investigators. The protocol has IRB approval at Memorial Sloan Kettering Cancer Center and five additional sites and executed agreements at two sites.

Comparative effectiveness of surgery vs stereotactic radiation therapy for stage I lung cancer


Benjamin D. Kozower, MD, MPH

TSOG PI: Benjamin D. Kozower, MD, MPH

Washington University in St. Louis

This proposal was previously presented during TSOG's first request for proposals in 2017. Since then, the revised NCI R01 has a fundable score and a projected start date in 2022 Q2 at the study's initiating site, Washington University. This NCI-funded multicenter prospective cohort study is designed to compare the effectiveness of surgery versus SBRT on stakeholder-selected outcomes in patients with clinical stage I NSCLC. The trial plans to develop prediction models for treatment outcomes for an individual patient with stage I NSCLC. This study can finally provide some high-level prospective evidence for the treatment of early-stage lung cancer. Participating TSOG sites are Washington University, Memorial Sloan Kettering Cancer Center, MD Anderson Cancer Center, University of Toronto/University Health Network, and Duke University. There are a total of seven sites participating in this trial, which includes non-TSOG sites Cleveland Clinic and Emory University.

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TSOG Audits

Since 2019, TSOG protocols have been audited, with leadership from the study initiating sites. Washington University has been audited for the TSOG 101 ctDNA study by the Memorial Sloan Kettering research team. MD Anderson Cancer Center, University of Montreal, Washington University, University of Michigan, and Brigham and Women's Hospital have all been audited by the Memorial Sloan Kettering research team for the TSOG 102 GGO study. The University of Toronto has been audited for the TSOG 103 colorectal metastases study by the MD Anderson research team with plans to audit Thomas Jefferson University in Fall 2022.

Participating sites are provided notice of the audit and are given guidelines for preparation weeks in advance. A formal announcement is sent to the participating site PI and research team, indicating areas to be reviewed. The audit consists of a review of participant cases enrolled onto the protocols, data entry, source, and regulatory documentation. All findings are summarized in a report shared with the sites' research teams as well as the TSOG Chair, Dr. David Jones.

Since 2020, the overall ratings for each of the following audit components—regulatory binder review, informed consent procedures, and participant case review—were found to be acceptable, with some areas identified for follow-up. The areas identified for follow-up are corrected by the participating sites within 1 to 2 weeks of receiving the report from the initiating site conducting the audit. All TSOG study initiating sites will continue to conduct regular audits at participating study sites as a way to monitor the data and regulatory quality of all of our studies.

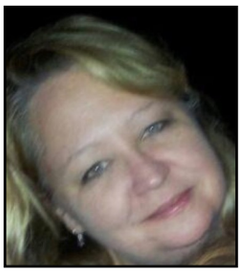
TSOG Site Coordinator Working Group

As TSOG's first subcommittee, the Site Coordinator Working Group continues to meet monthly, with its nineteenth meeting taking place January 2022. The working group's topics focus on areas such as identifying and addressing barriers to protocol activation and accrual for all TSOG trials, as well as generating ideas to improve communication across the TSOG community. Each meeting is used as a platform for site coordinators to address questions and present updates on trials. The group receives training on TSOG protocol–related items such as database entry and brainstorms ideas on managing TSOG protocol–related matters. In 2022, the Site Coordinator Working Group will be involved in the review of new and upcoming TSOG protocols.

Spotlight

Washington University in St. Louis

All TSOG Site Coordinators are noteworthy in their contributions to TSOG; however, we would like to highlight the efforts of Laura Carpenter, RN, from Washington University.



Laura Carpenter, RN

Laura has worked at Washington University for several years. She has worked as a clinical research nurse in radiation oncology and as a review coordinator with the site's IRB. In her current role as a thoracic surgery clinical research specialist, which she has held for over 2 years, Laura works closely with TSOG institutional PI Benjamin Kozower, MD. She has been an integral part of the activation of his upcoming NCI-funded multicenter trial. Not only is Laura dedicated to helping others in her Washington University research group, she also supports other cancer research centers in enrollment and compliance. Laura's positive demeanor and strong work ethic keep her research team moving and accomplishing their goals, given the diverse portfolio, including external NIH and VA funding, internal research and quality improvement projects, and work with collaborative groups such as TSOG. Washington University is one of the nine original TSOG sites and was the first site to activate all three initial TSOG protocols. There is no doubt this would not have been accomplished without Laura's efforts. She is a star!

If you are interested in learning more about TSOG, please visit the TSOG page on the AATS website or contact TSOG Project Coordinator Maria Singh, singhm1@mskcc.org.