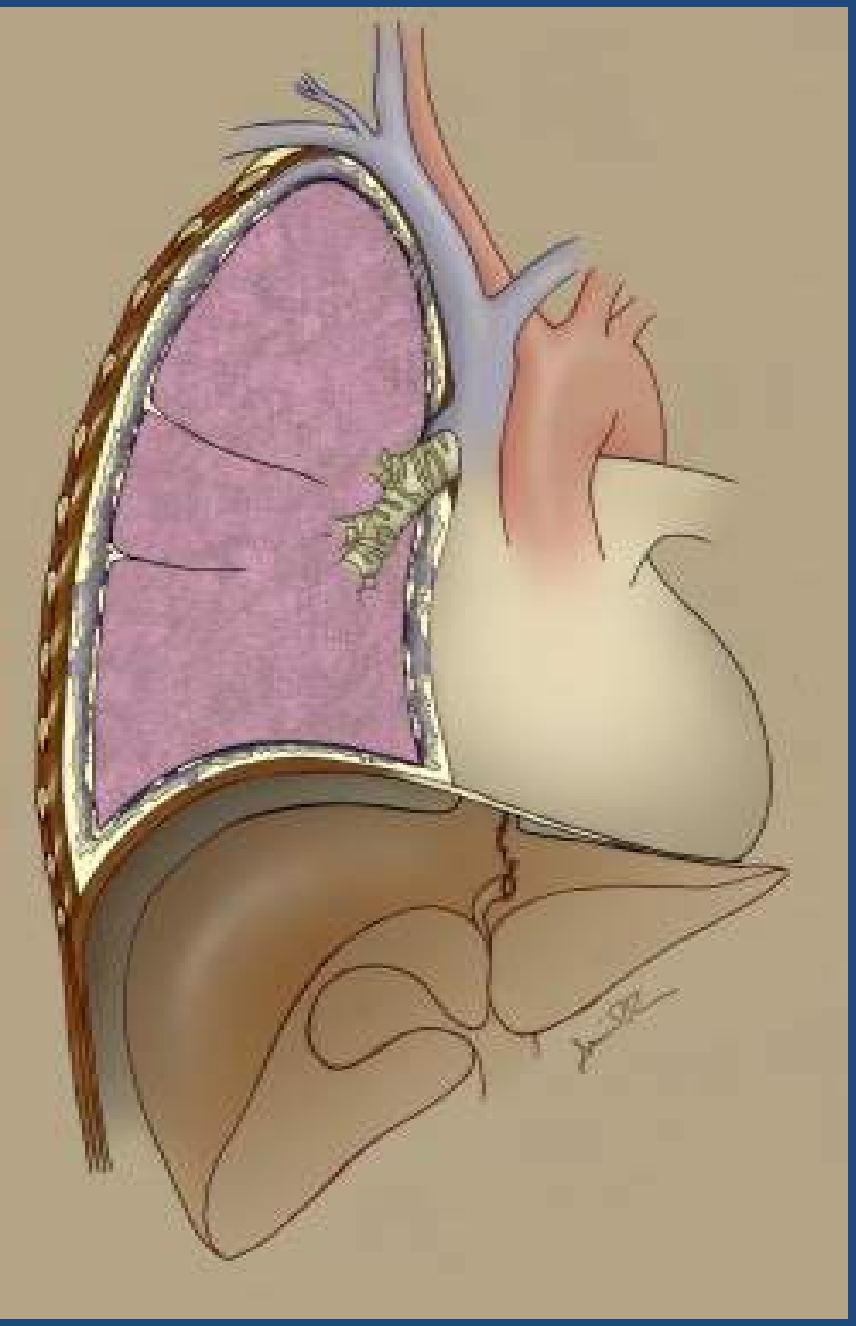


SWOG Clinical Trials Lung Committee

Boris Sepesi MD
Slides are courtesy of Wayne Hofstetter, MD
GTSC 2022

SWOG Lung Trials

Open Trials

Stage IB-IIIA NSCLC

- Alchemist- Phase III- Adjuvant SOC +/- Targeted Agent or IO in Completely Resected NSCLC

ALCHEMIST Trial Structure

ALCHEMIST is an umbrella trial for

1. A151216; Screening Trial for targeted adjuvant therapy post R0 resection of early stage NSCLC
2. A081105; EGFR inhib v placebo, Closed
3. E4512; ALK inhib v placebo, fully accrued
4. *EA5152; ANVIL - Nivolumab v observation*, Closed to accrual
5. *A081801; Chemo-Pembro*, still active

Trial Metrics: ALCHEMIST (CTSU 3/26/2021)		
Metric	**Value**	**Protocol Status**
Total sites open for A151216	1220 (1196)	Active
Total pts registered to A151216	6013 (5957)	
Total pts registered to A081105	390 (390)	Closed to Accrual
Total pts registered to E4512	125 (125)	Active
Total pts registered to EA5142	935 (935)	Closed to Accrual
Total pts registered to A081801*	80	Active

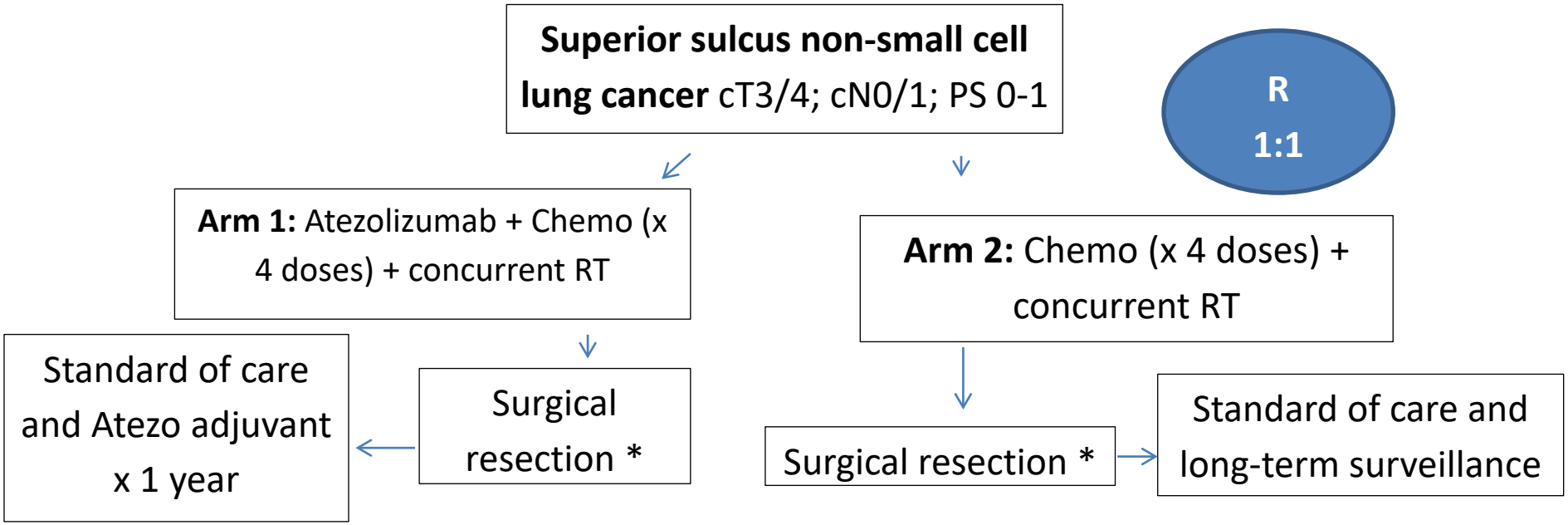
** reported separately from Alliance Statistical Office*

S1934: NASSIST

Neoadjuvant Chemoradiation +/- Immunotherapy before Surgery for Superior Sulcus Tumors

A Randomized Phase II Trial of Trimodality +/- Atezolizumab in Resectable Superior Sulcus Non-Small Cell Lung Cancer

S1934: Now Approved



Arm 1: Preoperative investigators' choice platinum doublet chemotherapy (platinum with etoposide/ paclitaxel/ pemetrexed) + atezolizumab iv q3 weeks x4, + 61.2 Gy concurrent radiation; surgical resection.
Arm 2: same, minus atezolizumab.

*For patients who do not undergo surgical resection, one year of consolidation durvalumab will be strongly recommended as standard of care. Data from these patients, typically approximately 20% of superior sulcus trial patients, will be collected and evaluated in exploratory comparative analyses of definitive non-surgical treatment in the setting of immunotherapy.

Objectives

Primary

- pCR rate between patients randomized to conventional trimodality therapy, with or without Atezolizumab.

Secondary objectives

- OS
- Event-free survival
- Recurrence free survival (RFS)
- Surgical resection and complete (R0) resection rates
- PFS among patients who do not undergo surgical resection
- Frequency, severity of toxicities

Other objectives

- Bank radiologic images for future research
- Bank blood and tissue for future research
- Evaluate the frequency and severity of general pain, cough, shortness of breath and fatigue measured by the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) by treatment arm
- Evaluate the association between major pathologic response (MPR)* and overall survival by treatment arm

Children's Oncology Group AOST2031: A Phase 3 Randomized Controlled Trial Comparing Open vs Thoracoscopic Management of Pulmonary Metastases in Patients with Osteosarcoma

John J. Doski MD

COG Surgery, UT Health San Antonio

Fall 2021 SWOG Virtual, again

CHILDREN'S ONCOLOGY GROUP

COG Study AOST2031

- A COG Study randomizing surgical management of oligometastatic (≤ 4 lesions) pulmonary metastatic osteosarcoma to open or thoracoscopic surgery
- Protocol involves disciplines of Surgery, Imaging, Biology, and Quality of Life. (Correlative studies in Biology, imaging, and QOL)

AOST2031 Overview

- Eligibility: <50 years of age; control of primary disease, pulmonary only metastatic osteosarcoma with ≤4 lesions per hemithorax. (=oligometastatic)
- At least one ≥3 mm lesion: peripheral, appearance consistent with metastases, no central lesions. Amenable to wedge resection or segmentectomy, no anatomic resections nor blurry pleural margin.
- Real time Preop Central Radiologic Review to confirm eligibility
- Institutional localization efforts permitted; data to be collected.
- Randomized to open or VATS, surgery within 28 days of imaging.
- QOL studies preop, post op @ 48hrs, 7-14 days, and 4-6wks
- First postop Chest CT at 8-12 weeks, submit for central review.

Primary and Secondary Objectives AOST2031

- **Primary**
  - To determine if open surgical resection is superior to thoracoscopic resection for thoracic event free survival (tEFS) in patients with resectable oligometastatic pulmonary osteosarcoma
- **Secondary**
  - To determine if open surgical resection is superior to thoracoscopy for event free survival (EFS) in patients with resectable oligometastatic pulmonary osteosarcoma.
  - To determine if open surgical resection is superior to thoracoscopy for overall survival (OS) in patients with resectable oligometastatic pulmonary osteosarcoma.
  - To determine if thoracoscopy is superior to open surgical resection for post-operative pain interference in patients with resectable oligometastatic pulmonary osteosarcoma.

Surgical and Imaging Exploratory Aims

- To compare 30-day rates of perioperative surgical complications for both open surgical resection and thoracoscopy.
- To compare patterns of recurrence (ipsilateral and/or contralateral) in patients who undergo open or thoracoscopic resection for unilateral or bilateral pulmonary metastases.
- To describe the use of localization techniques and its relationship with both surgical approach and pathologic findings.
- To describe the relationship between the preoperative chest computed tomography (CT) imaging, intraoperative surgical findings, and pathologic results, comparing radiological features to the presence of viable tumor.