


Rush University Medical Center

Rush Lung Center: Research

External-to-Rush Edition

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Abby Goerge
Clinical Research Coordinator

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1 Who is Rush Lung Center Research?

Who is Rush Lung Center Research?

- Thoracic Surgery
- Lung Medical Oncology
- Pulmonary

2 Thoracic Clinical Trials

Thoracic Clinical Trials

Role of Circulating Tumor DNA (ctDNA) From Liquid Biopsy in Early Stage NSCLC Resected Lung Tumor Investigation (LIBERTI)

- [clinicaltrials.gov: NCT03553550](https://clinicaltrials.gov/ct2/show/study/NCT03553550)
- The purpose of this research study is to learn more about changes in cell-free tumor DNA in blood samples, also known as a liquid biopsy, as they relate to treatment and response to treatment.

Implementing Tobacco Treatment in Low Dose CT Lung Cancer Screening Sites

- [clinicaltrials.gov: NCT03315910](https://clinicaltrials.gov/ct2/show/study/NCT03315910)
- This study is to help determine the most effective type or combination of treatments to offer patients seeking lung cancer screening who are smokers to help them reduce the number of cigarettes they smoke, or quit smoking.

Study to evaluate perioperative circulating tumor DNA as a prognostic biomarker in patients undergoing neoadjuvant therapy for resectable non-small cell lung cancer.

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A Registry for Patients with Multifocal Ground Glass Opacities (GGOs)

- [clinicaltrials.gov: NCT03802981](https://clinicaltrials.gov/ct2/show/study/NCT03802981)

Thoracic Clinical Trials

3 Trials In Progress

- **Prolonged Air Leak Registry and Blood Patch Intervention Trial**
 - The primary objectives of this project are to generate convincing evidence supporting the Prolonged Air Leak Score as a clinically useful tool to risk-stratify patients for PAL and establish the autologous blood patch (ABP) as a safe and effective means of treating postoperative air leaks.

- **A Randomized Study Evaluating Patients Discharged with Indwelling Chest Tube and Valve**
 - The purpose of this research is to gather information about the effectiveness of antibiotics and closer monitoring on decreasing infections and hospital readmissions when patients discharge from the hospital with a chest tube and valve in place.

- **Role of Short Term Preoperative Inspiratory Muscle Training for Preventing Respiratory Complications after Pulmonary Lobectomy**
 - The primary objective of this study is to investigate the effectiveness of a preoperative, short course, home-based IMT regimen in reducing postoperative respiratory complications in patients undergoing pulmonary lobectomy.

3 Cancer Center Clinical Trials

Cancer Center Clinical Trials

We have 3 types of Clinical Trial Treatment Options:

Surgical (Resectable)

- This option is available for patients who have resectable disease and can be removed by surgery.

Non-surgical (Unresectable)

- This option is available for patients who are not resectable candidates, but can be treated with chemotherapy and immunotherapy.

Radiation

- This option is for patients eligible for radiation treatment.

Our clinical trials include combinations of all 3 types of treatment.

Cancer Center Clinical Trials: Resectable Patient Trials

- **Chemoradiation Plus Durvalumab Followed by Surgery Followed by Adjuvant Durvalumab in Patients With Surgically Resectable Stage III (N2) Non-Small Cell Lung Cancer**
 - [clinicaltrials.gov: NCT03871153](https://clinicaltrials.gov/ct2/show/study/NCT03871153)
 - This is an open label, multi-institutional, single arm Phase II trial. All patients will be treated with Carboplatin, Paclitaxel, Durvalumab and Radiation. All patients with non-PD after induction therapy who remain surgical candidates will undergo surgical resection 4-12 weeks following induction therapy.
- **A Study of Neoadjuvant/Adjuvant Durvalumab for the Treatment of Patients With Resectable Non-small Cell Lung Cancer**
 - [clinicaltrials.gov:NCT03800134](https://clinicaltrials.gov/ct2/show/study/NCT03800134)
 - Arm 1: Durvalumab ((MEDI4736) in concurrence with platinum-based chemotherapy.
 - Arm 2: Placebo in concurrence with platinum-based chemotherapy.
- **Study of Efficacy and Safety of Canakinumab as Adjuvant Therapy in Adult Subjects With Stages AJCC/UICC v. 8 II-III A and IIIB (T>5cm N2) Completely Resected Non-small Cell Lung Cancer**
Acronym: CANOPY-A (Canopy-A)
 - [clinicaltrials.gov: NCT03447769](https://clinicaltrials.gov/ct2/show/study/NCT03447769)

Cancer Center Clinical Trials: Unresectable Patient Trials

- **Phase 2 Platform Study in Patients With Advanced Non-Small Lung Cancer Who Progressed on First-Line Osimertinib Therapy (ORCHARD)**
 - [clinicaltrials.gov: NCT03944772](https://clinicaltrials.gov/ct2/show/study/NCT03944772)
- **Study to Assess Safety and Efficacy of the Second Mitochondrial-derived Activator of Caspases (SMAC) Mimetic Debio 1143 (SMARTPLUS-106)**
 - [clinicaltrials.gov: NCT04122625](https://clinicaltrials.gov/ct2/show/study/NCT04122625)
- **Pembrolizumab in Combination With Platinum-Based Chemotherapy in Non-Small Cell Lung Cancer (NSCLC) Patients With Targetable Genetic Alterations, Previously Treated With Appropriate Targeted Agents, With Progressive Disease**
 - [clinicaltrials.gov: NCT03242915](https://clinicaltrials.gov/ct2/show/study/NCT03242915)

Cancer Center Clinical Trials: Unresectable Patient Trials

- **Study of Osimertinib With and Without Ramucirumab in Locally Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC)**
 - [clinicaltrials.gov: NCT03909334](https://clinicaltrials.gov/ct2/show/study/NCT03909334)
- **Unresectable Stage IIIA/IIIB Non-small Cell Lung Cancer (NSCLC)**
 - [clinicaltrials.gov: NCT03285321](https://clinicaltrials.gov/ct2/show/study/NCT03285321)
 - This study is an open label, multicenter, randomized phase II trial of consolidation immunotherapy with either nivolumab alone or the combination of nivolumab and ipilimumab following concurrent chemoradiation in patients with unresectable stage III NSCLC.
- **A Study to Evaluate the Efficacy and Safety of Anamorelin HCl for the Treatment of Malignancy Associated Weight Loss and Anorexia in Adult Patients With Advanced Non-Small Cell Lung Cancer (NSCLC)**
 - [clinicaltrials.gov: NCT03743051](https://clinicaltrials.gov/ct2/show/study/NCT03743051)

Cancer Center Clinical Trials: Radiation Patient Trials

- **Maintenance Chemotherapy With or Without Local Consolidative Therapy in Treating Patients With Stage IV Non-small Cell Lung Cancer**
 - [Clinicaltrials.gov: NCT03137771](https://clinicaltrials.gov/ct2/show/study/NCT03137771)
- **Chemoradiation With or Without Atezolizumab in Treating Patients With Limited Stage Small Cell Lung Cancer**
 - [Clinicaltrials.gov: NCT03811002](https://clinicaltrials.gov/ct2/show/study/NCT03811002)
- **A Randomized Two Arm Phase II Trial of Pembrolizumab Alone or Sequentially Following Single Fraction Non-ablative Radiation to One of the Target Lesions, in Previously Treated Patients With Stage IV NSCLC**
 - [Clinicaltrials.gov: NCT02658097](https://clinicaltrials.gov/ct2/show/study/NCT02658097)
- **Chemoradiation Followed by Durvalumab in Poor Risk and/or Elderly Patients With Stage III NSCLC (ESR1814205)**
 - [Clinicaltrials.gov: NCT04441138](https://clinicaltrials.gov/ct2/show/study/NCT04441138)

4 Investigator Initiated Studies

Ongoing Investigator-Initiated Studies

1 IRB Approved (1 of 3)

- **Endobronchial Valves for Air Leak Human Device Exemption (ORA: 19042908)** approved 6/6
 - PI Geissen
- **Registry of Extra Corporeal Membrane Oxygenation (ECMO) during COVID-19 Infection (ORA: 20040401)** approved 4/23;
 - PI Alex/Tatooles
 - **Hypothesis:** Although ECMO can provide oxygenation, ventilation and even hemodynamic support, outcomes remain unknown during COVID-19 infection. To assess these outcomes, we aim to participate in a multicenter national registry of such patients to determine clinical variables associated with morbidity and mortality.
- **Smoking Cessation and Lung Cancer Survey: Does surgical intervention promote smoking cessation? (ORA: 19091002)** administered via REDCap, currently 107 subjects enrolled;
 - PI: Alex/Seder
 - **Hypothesis:** Surgical intervention is a promoting factor for smoking cessation and if more resources should be directed towards smoking cessation for patients that had surgery.

Ongoing Investigator-Initiated Studies

1 IRB Approved (2 of 3)

- **Respiratory Muscle Index as a tool for Pre-Op Risk Stratification in Cardiothoracic Surgery (ORA: 19120802)** approved 2/13;
 - PI Karush
 - **Hypothesis:** patients diagnosed with sarcopenia (based on SMI cut off values reported in Martin et al) and NLR >4 have a higher incidence of postoperative complications, increased rates of 30-day mortality, and worse disease free and overall survival.
- **Effect of Marijuana Usage on Outcomes of Patients Presenting with Primary Spontaneous Pneumothorax (ORA: 19111702)** approved 2/3;
 - PI Karush
 - **Hypothesis:** Marijuana smokers will have higher rates recurrent pneumothorax than non-marijuana smokers.

Ongoing Investigator-Initiated Studies

1 IRB Approved (3 of 3)

- **Identifying Discrepancies in Access to Care in Geographically Similar Populations of Lung Cancer Patients (ORA: 19011506)** approved 10/14/2019;
 - PI Geissen
 - **Hypothesis:** Patients who are non-English speaking and undocumented will demonstrate significant delays between initial presentation and diagnosis, and diagnosis and treatment, which will portend upstaged pathological staging and therefore worse prognosis as compared to a matched cohort of similar clinically staged patients.
- **An Evaluation of Sarcopenia and Neutrophil-to-Lymphocyte Ratio as a Predictor of Post Operative Outcomes in Lung Cancer (ORA: 19121401)** approved 2/17;
 - PI Seder
 - **Hypothesis:** patients diagnosed with sarcopenia (based on SMI cut off values reported in Martin et al) and NLR >4 have a higher incidence of postoperative complications, increased rates of 30-day mortality, and worse disease free and overall survival.

Ongoing Investigator-Initiated Studies

2 In Progress (1 of 2)

- **Brigham Collaboration: status**—received partially executed DUA issued from Brigham 6/8, being sent to our legal by Dawn Paulsen (she is the Regulatory Manager for CCTO and manages Dr. Borgia's ORAs)
- **Megabot Project: status**—statisticians running second analysis, due to Seder July 1. Submitting to STS August 11
 - PI: Seder
 - **Hypothesis:** We hypothesize that, in patients with early-stage (stage I or II) NSCLC and a BMI ≥ 30 , elective anatomic lung resections performed by RATS will result in a lower rate of conversion to thoracotomy and lower 30-day morbidity and mortality rates than those performed VATS.
- **Primary Lymph node Study: status**—analysis ongoing with Tempus, 60 patients.
 - PI: Seder
 - **Hypothesis:** In patients with node-positive lung adenocarcinoma, the molecular profile of LNM may be useful for prognosticating clinical outcomes.
- **Wedges Study:** prediction on recurrence based on wedge, 100 patients. PI: Seder

Ongoing Investigator-Initiated Studies

2 In Progress (2 of 2)

- **Non-home discharge Study:**
 - PI: Karush/Seder
 - **Hypothesis:** NHDS utilizes simple and widely available preoperative parameters can reliably identify patients who are at increased risk for non-home discharge following resection; receiving through PUF.
- **Benign Endobronchial Neoplasms (ORA: 20052703):** 25 retrospective review observing diagnosis and survival outcomes:
 - PI Insler/Seder
- **Neutrophil-to-Lymphocyte Ratio as a Predictor of the Development of Severe Disease in Hospitalized COVID-19 Patients**
 - PI: Wakefield/Seder
 - **Hypothesis:** NLR can reliably prognostic development of severe disease; 1) high degree of inflammation who develop severe disease when hospitalized. 2) Highly NLR values combined with high inflammatory markers will be associated with worse outcomes (ICU stay length, need for MV, MV duration, ECMO, and death)

5 Publications 2018-2020

Publications 2018-2020

Department Publication Total: (excluding chapters)

- 2018: 12
- 2019: 13
- 2020 current: 6

Publications 2018-2020

*****Note: publications with multiple physicians not be listed more than once, regardless of author. If there is a publication missing it should be listed under another physician.***

Liptay

1. Tarhoni I, Fhied CL, Pool M, Liptay MJ, Bonomi P, Seder CW, Borgia JA. Development of bead based multiplexed immunoassay for evaluation of midkine, syndecan-1, and ANGPTL4 in patient serum. J Immunoassay Immunochem 2018;39(1):84-98.
2. Kanangat S, Seder CW, Pergande MR, Lobato GC, Fhied CL, Raouf MF, Liptay MJ, Borgia JA. Circulating histocompatibility antigen (HLA) gene products may help differentiate benign from malignant indeterminate pulmonary lesions. Hum Immunol 2018; 79(7):558-563.

Seder

Publications

1. Seder CW. Lung Cancer Screening is here to stay, but does it pay? J Thorac Cardiovasc Surg 2018;155(1):426-427.
2. Seder CW, Mahon B, Hennon M, Thomas M, LeVea CM, Matkowskyj KA, Krishna M, Medairos R, Macke RA, Basu SA, Blasberg JD. Depth of Muscularis Propria Invasion Does Not Prognosticate Survival in T2 Esophageal Adenocarcinoma. Anticancer Res 2018; 38(4):2195-2200.
3. Seder CW, Raymond D, Wright CD, Gaissert HA, Chang AC, Clinton S, Becker S, Puri V, Welsh RJ, Burfeind W, Fernandez FG, Brown LM, Kozower BD. The Society of Thoracic Surgeons General Thoracic Surgery Database 2018 Update on Outcomes and Quality. Ann Thorac Surg 2018; 105(5):1304-1307

Publications 2018-2020

Seder contined:

5. Song KJ, Colman M, Myers JA, Seder CW. Transdiaphragmatic Migration of a Spinal Fixation Rod into the Lung. Lung 2018; 196(3):369-371.
6. Davison MA, Norton DN, Popoff AM, Seder CW, March RJ. Hemolysis Following Wrap Aortoplasty for Type A Aortic Dissection Repair: Case Report and Review of the Literature. Vasc Med 2018; 23(4):400-406.
7. Seder CW. Blazing New Trails: Initial Efforts to Create a Joint STS-ESTS Dataset. J Thorac Dis 2018;10(Suppl 29):S3507-S3510.
8. Schieman C, Seder CW, D'Amico TA, Grondin SC. Thoracic Surgical Training in North America: Contrasting Thoracic Surgery Residencies in the United States and Canada. J Cardiovasc Thorac Surg 2018;156(6):2379-2387.
9. Puri V, Gaissert HA, Wormuth DW, Grogan EL, Burfeind WR, Chang AC, Seder CW, et al. [Defining Proficiency for Society of Thoracic Surgeons Participants Performing Thoracoscopic Lobectomy](#). Ann Thorac Surg 2019; 107(1):202-208.
10. Shersher DD, Seder CW. [Crafting a modern surgeon-scientist in cardiothoracic surgery](#). J Thorac Dis 2018;10(Suppl 26):S3220-S3221.
11. Seder CW, Magee MJ, Broderick SR, Brown LM, Blasberg JD, Kozower BD, et al. [The Society of Thoracic Surgeons General Thoracic Surgery Database 2019 Update on Outcomes and Quality](#). Ann Thorac Surg 2019;107(5):1302-1306.

Publications 2018-2020

Seder continued:

12. Harmon S, Seder CW, Chen S, Traynor A, Jeraj R, Blasberg JD. Quantitative FDG PET/CT May Help Risk-Stratify Early-Stage Non-Small Cell Lung Cancer Patients At Risk For Recurrence Following Anatomic Resection. *J Thorac Dis* 2019;11(4):1106-1116.
13. Seder CW. Everyone Hates Chest Tubes. *Semin Thorac Cardiovasc Surg* 2019 [Epub ahead of print]
14. Seder CW, Basu S, Ramsay T, Rocco G, Blackmon S, Liptay MJ, et al. A Prolonged Air Leak Score for Patients Undergoing Lung Cancer Resection: An Analysis of the Society of Thoracic Surgeons General Thoracic Surgery Database. *Ann Thorac Surg* 2019 [Epub ahead of print]
15. Oliveros E, Collado FM, Poulin MF, Seder CW, March R, Kavinsky CJ. Percutaneous right ventricular assist device using the Tandem Heart Protek Duo: real world experience. *J Structural Heart Dis* 2019 [*In press*]
16. Yakupovich A, Davison MA, Kharouta MZ, Turian J, Seder CW, et al. Heart Dose and Coronary Artery Calcification in Patients Receiving Thoracic Radiation for Lung Cancer. *J Thorac Dis* 2019 [*In press*]
17. Coughlin JM, Zang Y, Terranella S, Alex G, Karush JM, Geissen N, et al. Understanding Barriers to Lung Cancer Screening in Primary Care. *J Thorac Dis* 2019 [*Under review*]
18. Broderick SR, Grau-Sepulveda M, Kosinski AS, Kurlansky PA, Shahian DM, Jacobs JP, et al. The Society of Thoracic Surgeons Composite Score Rating for Pulmonary Resection for Lung Cancer. *Ann Thorac Surg* 2020;109(3):848-855.

Publications 2018-2020

Seder continued:

19. Seder CW. Has the Time Finally Arrived for Radiofrequency Ablation to Enter the Game? Semin Thorac Cardiovasc Surg 2020 [*epub ahead of print*]
20. Insler JE, Seder CW, Pool M. A Case of Vanishing Thymoma. Ann Thorac Surg 2020 [*epub ahead of print*]
21. Eby ME, Seder CW. The Landmark Series: Multimodality Therapy for Stage IIIA Non-Small Cell Lung Cancer. Ann Surg Onc 2020 [*Epub ahead of print*]
22. Seder CW. Try acting like a normal human being. J Thorac Cardiovasc Surg 2020 [*Epub ahead of print*]

Publications 2018-2020

Seder continued:

Chapters:

1. Seder CW, Liptay MJ. Staging and Restaging of Lung Cancer. In Adult Chest Surgery, 3rd Edition, New York, NY: McGraw-Hill (2018)
2. . Coogan A, Jordano L, Liptay MJ, Seder CW. Tracheal Chondrosarcoma: A Case Report. 100 Interesting Cases in Thoracic Surgery, London, England: CRC Press (2020).
3. Alex, G, Seder CW, Ukoha U. The Surgical Treatment of Pulmonary Echinococcosis: A Case Report. 100 Interesting Cases in Thoracic Surgery, London, England: CRC Press (2020).
4. Jordano L, Seder CW, Chmielewski GW. Robotic Stapled Plication of a Left Hemi Diaphragm Eventration: A Case Report. 100 Interesting Cases in Thoracic Surgery, London, England: CRC Press (2020).
5. Song K, Seder CW, Ukoha U. Mixed Cavernous Hemangioma-Lymphangioma of the Gastroesophageal Junction: A Case Report. 100 Interesting Cases in Thoracic Surgery, London, England: CRC Press (2020).
6. Coughlin J, Seder CW. Intralobar Pulmonary Sequestration with Aberrant Venous Drainage: A Case Report. 100 Interesting Cases in Thoracic Surgery, London, England: CRC Press (2020).
7. Gallo K, Alex G, Seder CW. Concurrent Congenital Diaphragmatic Hernia and Extralobar Pulmonary Sequestration: A Case Report. 100 Interesting Cases in Thoracic Surgery, London, England: CRC Press (2020).
8. Lewin G, Ravanbakhsh S, Seder CW, Ukoha U. Getting the “Gist” of Esophageal GISTs: A Case Report. 100 Interesting Cases in Thoracic Surgery, London, England: CRC Press (2020).
9. Redmond A, Anderson EP, Seder CW, Geissen NM. Malignant Solitary Fibrous Tumor of the Pleura: A Case Report. 100 Interesting Cases in Thoracic Surgery, London, England: CRC Press (2020).
10. Eby ME, Seder CW. Is Surgical Management of Flail Chest Effective? Difficult Decisions in Thoracic Surgery-An Evidence Based Approach (2020)

Publications 2018-2020

Karush

1. Karush J, Seder CW. NextGen Training Assessment Tools in Thoracic Surgery. Journal of Thoracic Disease. 2018; 10(8)
2. Karush J, Arndt A, Liptay M, et al. Improved False-Positive Rates and the Overestimation of Unintended Harm from Lung Cancer Screening. Lung. 2019. Epub ahead of print.
3. Karush J, Friedberg J, Liptay M. Chapter 53: Overview of Benign and Malignant Disorders of the Upper Airways. Adult Chest Surgery, 3rd edition. 2019.

Publications 2018-2020

Arndt

1. Arndt AT. For Esophageal Cancer, Behind Every Successful Man... [published online ahead of print, 2020 Mar 30]. *Ann Surg Oncol*. 2020;10.1245/s10434-020-08393-x. doi:10.1245/s10434-020-08393-x

2. Oesophago-Gastric Anastomosis Study Group on behalf of the West Midlands Research Collaborative. International Variation in Surgical Practices in Units Performing Oesophagectomy for Oesophageal Cancer: A Unit Survey from the Oesophago-Gastric Anastomosis Audit (OGAA). *World J Surg* 2019 [Epub ahead of print].

PMID: 31332491

3. Song KJ, Arndt AT. Is a novel nomogram better than TNM staging at predicting survival in Siewert type 2 adenocarcinoma? *Ann Surg Oncol* 2019;26(5):1182-1183.

PMID: 30771117

4. **Arndt AT**. A little bit of cancer is still cancer: is it time for lymph node micrometastases in non-small cell lung cancer to get their due? *Ann Surg Oncol* 2018;25(13):3781-3782.

Geissen

1. Geissen NM. Does Complete Pathologic Response Come to Those Who Wait? *Ann Surg Oncol*. 2019;26(3):707-708. doi:10.1245/s10434-018-7084-3

Thank you.



Rush University Medical Center

Excellence is just the beginning.