

Thoracic Oncology (Lung Cancer) Translational Center of Excellence **Overview**

Clinical Director: Corey Langer, MD

Translational Director: Steven Albelda, MD

Project / Database Manager: Christiana Davis, MD

Abramson Cancer Center



Penn Medicine

Recent Hires

- **Project/Database Manager,**

- **Dr. Saman Ahmed**, hired August 1, 2014 was actively involved until May 2015, when she left Penn for Pulmonary Fellowship at Roswell Park.
- **Dr. Christiana Davis**, her replacement started October 1, 2015.
 - Non-practicing MD with interests in medical communication, datasets, identifying trends and translating tumor data into improved outcomes for cancer patients.
 - Keeping tabs on all our projects
 - Previously worked on Program Projects at Penn.

- **Clinical Research Assistant,**

- **Seth Jeffries**, hired June 20, 2016.
- Responsibilities include obtaining informed consent, screening and enrolling patients for different study protocols centering on bio-correlatives in the field of thoracic immunoncology, as well as other aspects of thoracic oncology.
- Also assists with abstracting medical data from EMRs and entering abstracted data into databases

Major Areas of Focus

1. Translational lab-based studies to support clinical trials (CAR T cells and tumor microenvironment)
2. Clinical trials assessing immunotherapy in lung cancer
3. Databases to support lab-based studies and clinical trials and facilitate translational research

Translational Projects

- Analyze lung cancer tumor microenvironment
- Improve cancer detection during surgery
- Identify tumor-specific biomarkers to optimize selection of targeted therapies and to better predict response to therapy
- Delineate determinants of response to Checkpoint Inhibition
- Preclinical studies to determine if chimeric antigen receptor (CAR)-modified T cells function in lung cancer
- Preclinical studies to help overcome potential limitations of Adoptive T cell Transfer

Investigator Initiated Trials

Trial	Partner	Status
<p>Project 1A. Phase 1 Ad.TK Pleural Effusion Clinical Trial [Adenoviral vector encoding an immunogenic suicide gene injected intrapleurally]</p>	<p>Advantagene</p>	<ul style="list-style-type: none"> - Opened 10/13 - 22 screened/consented - 19 pts enrolled. Goal: - CRS in pt # 6 - Celecoxib added to mitigate toxicity - 13 pts accrued since amendment - Optimal dose identified - No new safety issues - Accrual completed Spring '16
<p>Project 1B. DNA Plasmid Vaccine Clinical Trial [Novel cancer-specific, hTert DNA vaccine has been developed; studied alone and in conjunction with DNA for IL-12 to serve as an adjuvant therapy]</p>	<p>Inovio</p>	<ul style="list-style-type: none"> - Opened 1/22/15 - Resected NSCLC (IB-IIIA) pts - Screened to date: 18 - # of active patients: 15 (15 completed Tx)

Investigator Initiated Trials

Trial	Partner	Status
<p>CAR-T Cells targeting Mesothelin for Lung Cancer and Mesothelioma</p>	<p>Novartis</p>	<ul style="list-style-type: none"> - Opened Summer, 2016 - Uses improved CAR targeted to mesothelin - NSCLC pts screened for mesothelin expression (increased likelihood with KRAS) - Phase 1 Trial- 3+3 design - If safe, groups will get pretreatment with cyclophosphamide - 3 MPM pts recruited to date
<p>Intra-tumoral Neoadjuvant Ad.TK for patients with high risk resectable lung cancer</p>	<p>Advantagene</p>	<ul style="list-style-type: none"> - To open Fall 2017 - Intratumoral injection of Ad.TK in resectable patients - Tumor then resected and analyzed 2 weeks later - Phase 1 Trial- 3+3 design

Investigator Initiated Trials

Trial	Partner	Status
<p>UPCC 25514-MK3475 Merck: Phase II Study of Pembrolizumab after Curative Intent Treatment for Oligometastatic Non-Small Cell Lung Cancer (PD-1)</p>	<p>Merck</p>	<ul style="list-style-type: none"> • PI: Joshua Bauml • Allows up to 4 metastatic sites • Pembro given for up to 1 yr after definitive Tx of mets • 42 pt accrued to date • Target n – 40 • Oral presentation at WCLC '17
<p>Phase II trial of consolidation pembrolizumab after concurrent chemotherapy and proton re-irradiation for thoracic recurrences of NSCLC</p>	<p>Merck</p>	<ul style="list-style-type: none"> • PIs: Christine Martin Ciunci and Abigail Berman • Opened Summer, 2017

Clinical Trials

Industry collaborations (Selected list)

Trial	N	Sponsor
<p>UPCC 06514-MK3475-021 Pembrolizumab in combination with chemotherapy or immunotherapy in patients with metastatic NSCLC (PD-1)</p>	20	Merck
<p>UPCC 06513-M 3475-010 Randomized trial of two doses of MK-3475 versus Docetaxel in previously treated subjects with NSCLC (PD-1)</p>	12	Merck
<p>UPCC 13514- Phase I/II Study of Pembrolizumab in combination with INCB024360 for Recurrent/Metastatic NSCLC or H&N</p>	4	Incyte
<p>UPCC 45914-Celgene-BMS-936558: Phase 1, Open-Label, Multicenter, Safety Study of Nivolumab (BMS-936558) in Combination with nab-Paclitaxel / Carboplatin in Stage IIIB/IV Non-Small Cell Lung Cancer</p>	3	Celgene
<p>UPCC 02516 – Stemcentrx: Rova T Open-label, Single-Arm, Phase 2 Study Evaluating Efficacy, Safety and Pharmacokinetics of Rovalpituzumab Tesirine (SC16LD6.5) for Third-line and Later Treatment of Relapsed or Refractory Delta-Like Protein 3-Expressing Small Cell Lung Cancer (TRINITY)</p>	4	Stemcentrx

Metrics of Success (1)

Thoracic Oncology: Comparative Volumes FY 2013 and 2014 and 2015 and 2016

Period	FY 2013	FY2014	FY 2015	FY 2016	% Increase*
Total Volume (unique pts)	2544	2908	3289	3549	39.5%
Total Volume Heme/Onc (PCAM and Presby)	1130	1271	1377	1490	31.8%
Total Volume Rad Onc (PCAM, Valley Forge)	491	593	753	846	72.3%
Total Volume Thoracic Surg (PCAM, CCH, PAH, Presby)	411	456	469	506	23.1%
Total Volume Pulmonary (PCAM)	512	588	690	707	38.1%

* % Increase: from 2013

Metrics of Success (2)

Thoracic Oncology

Protocol Accrual:

Therapeutic enrollment=181

Non-Therapeutic enrollment= 279

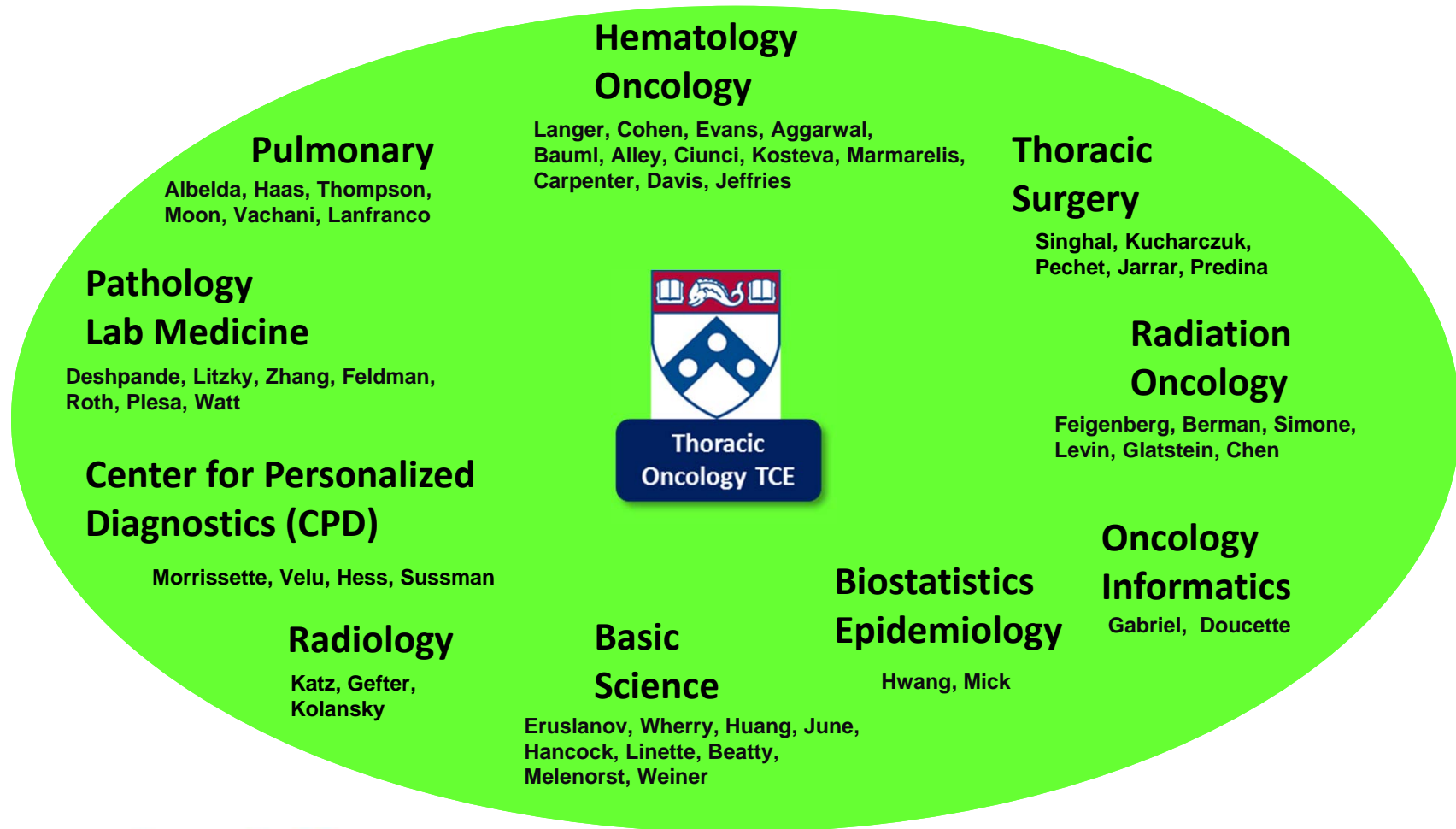
Accruals Thoracic Trials:

UPCC#	Trial	Accrual
25508	Trimodality	30
12512	Lung CTC	195
02515	Diagnostic CTC	76
28514	Flaxseed	26
15415	Gut microbiota	10
40914	RadVax- lung cohort	10
01516	NJ Pembro	1
NRG1308		15

Thoracic TCE: Goals

- **Publish and Disseminate Results of IITs and Industry Collaborations**
- **Expand our breadth of IO/IO combinations**
- **Complete vital Biocorrelative efforts with IOs, alone and in combination**
- **Expand Database initiatives**
- **Become self-sustaining (financially, scientifically)**
 - Grants
 - Philanthropy
 - Staffing and Infrastructure
- **Serve the needs of our Patients and the Careers of our Staff**

A Multi-investigator, Multidisciplinary Team



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