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**Precision Medicine in Lung Cancer:  
The Role of the Medically Integrated Team**

**Moderator:** J. Kevin Hicks, PharmD, PhD, FCCP  
**Speakers:** Theresa Boyle, MD, PhD  
Donna K. Gallenstein, BSN, RN, GERO-BC  
Dan Melzer, PharmD, BCOP  
Sonam Puri, MD

Moffitt Cancer Center, Tampa Florida



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**OBJECTIVES**

1. Discuss the role of immunotherapy and targeted therapy in the treatment of patients diagnosed with Stage III lung cancer.
2. Review the clinical evidence supporting therapies for *EGFR*-mutated lung cancer and *ALK*-rearranged lung cancer.
3. Describe what is next generation sequencing and application to lung cancer treatment in the adjuvant setting.
4. Detail a multidisciplinary approach to navigate patients through molecular profiling, interpretation of results, and proactive interdisciplinary processes for obtaining targeted therapy.

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 **DISCLOSURE**

The following relevant financial relationships from the past 24 months have been identified and disclosed for the following faculty of this CE activity:

- J. Kevin Hicks, PharmD, PhD, FCCP: Consultant for ARUP, Bristol-Myers Squibb (BMS), & Jackson Laboratories
- Theresa Boyle, MD, PhD: Principal Investigator (BMS), Speaker (BMS)
- Dan Melzer, PharmD, BCOP: Consultant for Daichii Sankyo & Takeda Pharmaceuticals; Speaker (Jazz Pharm), Honoraria (Dedham Group, OncoGenius Solutions)
- Sonam Puri, MD: Advisory Board Member (Pfizer, Takeda, BMS, Novocure, Oncohost)

No relevant financial relationships from the past 24 months have been identified and for the following faculty of this CE activity:

- Donna K. Gallenstein, BSN, RN, GERO-BC

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 **DISCLOSURE**

No relevant financial relationships from the past 24 months have been identified for the following faculty and planners of this CE activity:

- Mary K. Anderson, BSN, RN, OCN
- Tahsin Imam, PharmD
- Daisy Doan, PharmD

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**Clinical Case**

Mr. Joe Smith is a 58-year-old never smoker with a medical history of hypertension and gastroesophageal reflux disease.

He recently experienced shortness of breath and chronic cough. Initially treated for pneumonia with no improvement in symptoms. Imaging revealed a 5.1 cm mass in the left lower lobe of the lung along with lymphadenopathy. A biopsy was performed with pathology consistent for adenocarcinoma of lung primary.

He was diagnosed with T3N1M0 (Stage IIIA) lung adenocarcinoma.



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## Clinical Case


Mr. Smith contacted Moffitt Cancer Center to establish care.

Additional workup includes:

- Diagnostic testing: PET/CT, Brain MRI
- Genetic testing / Next Generation Sequencing
- Appointment with Medical Oncologist to review treatment options
- Appointment with Thoracic Surgeon to determine if cancer is resectable

A multidisciplinary approach can assist with optimally treating Mr. Smith

- Nurse Navigator
- Oncologist
- Molecular Pathology / Precision Medicine
- Pharmacy



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Mr. Smith is a 58-year-old never smoker who was recently diagnosed with Stage IIIA lung adenocarcinoma. He contacted Moffitt Cancer Center to establish care. An Oncology Nurse Navigator can help Mr. Smith with

1. Resources for financial assistance to pay for cancer treatment
2. Transportation to Moffitt Cancer Center
3. Scheduling necessary appointments including imaging, laboratory, and with oncologists
4. All of the above



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### Role of Nurse Navigator for Cancer Patients



Oncology Nurse Navigator is defined as "a professional RN with oncology specific clinical knowledge who offers individualized assistance to patients, families, and caregivers to help overcome healthcare system barriers."

Nurse navigators begin with prevention and screening activities through diagnosis, treatment and to the end of life

Oncology Nurse Navigators are the patient advocates based on clinical practices implanted in the facility.

Oncology Nurse Navigators will coordinate quality, patient-centered care through effective correspondences with the interdisciplinary team.

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### Nurse Navigator can Assist with Potential Problems & Barriers

- Health Insurance/Financial:**
  - Lack of insurance or assistance with Medicaid/Medicare
  - Difficulty paying for medications or prescription assistance
  - Need for medical equipment or supplies
- Transportation:**
  - Will they need transportation to Moffitt?
  - Will they need private services or ambulance services?
- Physical Needs:**
  - Childcare or elder care
  - Housing is poor or in need
  - Assistance with activities of daily living (ADLs): walkers, canes, wheelchairs
- Disease Management:**
  - Understanding of disease and potential treatment
  - Treatment compliance issues
- Communication/Cultural Needs:**
  - What is primary language?
  - Inability to read/write
  - Poor health literacy

Image courtesy of Moffitt Cancer Center

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### Nurse Navigator can Assist with Potential Problems & Barriers

- Support Services for Referrals:**
  - Social worker-advance directives, stress,
  - Dietician-poor oral intake
  - Fertility Preservation-young pts receiving chemo
  - Business office-insurance issues
  - Disability Office-FMLA paperwork
- Patient Digital Literacy:**
  - Can they email?
  - Can they text?
  - Capable of zoom visits?
- Goals for First Visit:**
  - Could be anything from diagnosis, treatment options, side effects or how long will I survive

Image courtesy of Moffitt Cancer Center

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### Presentation to Medical Oncology Clinic

**Discussion of results of testing ordered prior to appointment**

- PET CT with FDG avid LLL 5.1 cm mass with FDG avid left hilar LN
- MRI brain with no evidence of intracranial metastatic disease
- Moffitt Star Next Generation Sequencing (NGS) pending
- PD-L1 22C3 IHC 90%

↓

**Considerations for treatment decision making**

- Determination of surgical resectability is an important FIRST step
- Presence of EGFR or ALK alterations – important for determining choice of neoadjuvant , adjuvant and consolidation therapy

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**Recommendations**

- Multidisciplinary tumor board discussion
- Referral to interventional pulmonary for noninvasive mediastinal staging
- Referral to Thoracic Surgery to discuss possible surgical resection and neoadjuvant therapy if considered surgical candidate

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**Role of Adjuvant Immunotherapy to Treat Lung Adenocarcinoma Negative for Targetable Alterations**

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**Role of Durvalumab for Adjuvant Therapy In Unresectable NSCLC EGFR and ALK Wildtype**

- PACIFIC trial investigated durvalumab versus placebo after chemoradiation in those with unresectable NSCLC
  - 473 patients received durvalumab and 263 received placebo
- mPFS was 16.8 months with durvalumab versus 5.6 months with placebo
- The percentage of patients who were alive and progression free at 12 months was 55.9% (95% CI, 51 to 60.4) with durvalumab and 35.3% (95% CI, 29 to 41.7) with placebo.
- No data for those with unresectable Stage I-II disease

	No. of Events Total No. of Patients	Median PFS 95% CI	12 Mo PFS 95% CI	18 Mo PFS 95% CI
Durvalumab	214/475	16.8 (13.8-18.1)	55.9 (51.0-60.4)	44.2 (37.7-50.5)
Placebo	133/263	5.6 (4.6-7.8)	35.3 (29.0-41.7)	23.0 (18.9-28.0)

HR 0.52 (95% CI, 0.42-0.65) (one-sided P=0.0001)

No. at Risk  
Durvalumab: 475, 377, 302, 264, 199, 88, 44, 22, 4, 2  
Placebo: 263, 183, 106, 87, 52, 28, 11, 4, 1, 0

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**Role of Immunotherapy for Adjuvant Treatment in Resectable NSCLC EGFR and ALK Wildtype**

- Impower010 investigated atezolizumab after chemotherapy in resected Stage 1B (≥4 cm) - IIIA NSCLC
  - Atezolizumab improved disease-free survival compared with best supportive care among stage II-IIIa population (0.79; 0.64-0.96; p=0.020)
  - Those with PD-L1 of 1% had improved treatment survival (Hazard Ratio (HR) 0.66; 95% CI 0.50-0.88; p=0.0039)
  - Lancet. 2021 Oct 9;398(10308):1344-1357; PMID: 34555333
- PEARLS/KEYNOTE-091 investigated pembrolizumab after chemotherapy in resected Stage 1B (≥4 cm) - IIIA NSCLC
  - Median disease-free survival was 53.6 months in the pembrolizumab group versus 42.0 months in the placebo group (HR 0.76 [95% CI 0.63-0.91])
  - Lancet Oncol. 2022 Oct;23(10):1274-1286; PMID: 36108662

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**QUESTION 2**

Should genetic testing be performed to determine the presence of targetable driver mutations (e.g., *EGFR* or *ALK* mutations) in those with resectable Stage IIIA lung cancer?

- Yes
- No

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**Somatic Next Generation Sequencing (NGS)**

- What is it?**
  - Interrogation of a tumor's genome to determine what genetic changes may be present in the cancer
  - In cancer testing, NGS is often targeted to clinically important genetic changes
- What are the benefits?**
  - Opportunities for targeted therapy
  - Identify mutations resistant to specific therapies
  - Eligibility for clinical trials



MOFFITT STAR NGS™  
Solid Tumor  
Retrospective Research

MOFFITT Cancer Center | <https://www.moffitt.org/ncoda/ncoda-fall-summit-2024>  
Approved October 20, 2024

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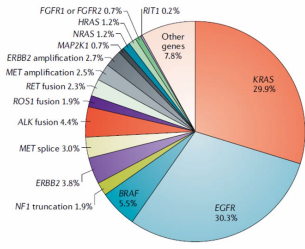
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**Somatic Next Generation Sequencing (NGS)**

Which clinically important genetic changes are detected in lung cancer?



Genetic Change	Percentage
EGFR	30.3%
KRAS	29.9%
Other genes	7.8%
BRAF	5.3%
ERBB2	3.8%
ALK fusion	4.4%
ROS1 fusion	1.9%
RET fusion	2.3%
MET amplification	2.5%
ERBB2 amplification	2.7%
MAP2K1	0.7%
NRAS	1.2%
FGFR1 or FGFR2	0.7%
NRAS	1.2%
RET	0.2%
MF1 truncation	1.9%
MET splice	3.0%

Shields F and Henschel J. Nat Rev Cancer 2019

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### Somatic Next Generation Sequencing (NGS)

- How is it performed?
  - DNA and RNA are extracted from a lung cancer sample from the patient
  - DNA and RNA are amplified, processed, and sequenced
  - Sequence is analyzed and filtered for genetic changes that might inform therapy
  - Molecular Pathologist reviews and interprets the results and issues a report

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### Why A Precision Medicine Clinical Service?

- Application of molecular biomarkers to oncology patient care for **therapeutic decision-making** and **clinical trial matching** is becoming increasingly complex
  - Somatic DNA sequencing of hundreds to thousands of genes
  - Somatic RNA sequencing for fusion events and gene expression
  - Immunohistochemistry including PD-L1, HER2, MMR
  - Other biomarkers including TMB, LOH, MSI, Mutational Signatures
  - Pharmacogenetics/germline testing
- There are gaps and barriers to integrating molecular biomarkers into patient care
- Dedicated Precision Medicine clinical service can help identify barriers and bridge gaps

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### Precision Medicine Clinical Service Can Help to Bridge Gaps

- Retrospective analysis of a data repository including Medicare claims and laboratory data for advanced NSCLC
- Estimated that **64%** of potentially eligible patients did not benefit from precision oncology therapies

Step	Practice Gap	Potentially Eligible Patients Remaining	% of Patients
1	Biopsy referral	1,000	4.0% (66/1000)
2	Biopsymen collection	760	14.6% (136/934)
3	Biopsymen evaluation/pathology	740	1.7% (14/798)
4	Biomarker test ordering	740	16.1% (142/784)
5	Biomarker test performance	642	14.4% (118/842)
6	Biomarker test result reporting	543	4.0% (216/524)
7	Treatment decision	356	29.2% (147/503)

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## Role of Adjuvant Targeted Therapy to Treat Lung Adenocarcinoma

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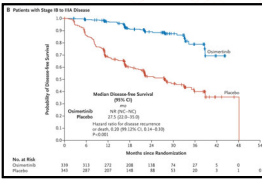
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### Role of Targeted Agents for Adjuvant Therapy - EGFR

- The ADAURA trial investigated osimertinib versus placebo in resected Stage IB-IIIa NSCLC harboring either EGFR exon 19 deletion or EGFR L858R (n=682 patients)
  - All patients eligible for adjuvant chemotherapy
    - ~ 40% did not receive adjuvant chemotherapy
  - 89% of the patients in the osimertinib group and 52% of those in the placebo group were alive and disease-free at 24 months.
- Stage II-IIIa disease appeared to have a greater benefit from osimertinib adjuvant therapy.
  - No data for Stage IIIB undergoing resection



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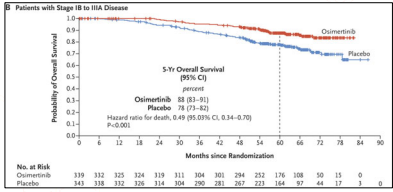
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### Role of Targeted Agents for Adjuvant Therapy - EGFR

- The 5-year overall survival was 88% in the osimertinib group and 78% in the placebo group
- Stage IB disease
  - 5-year OS 94% versus 88% (HR 0.44)
  - No data for Stage IA



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**Role of Targeted Agents for Adjuvant Therapy - Limitations**

- Limited data for Stage IA lung adenocarcinoma
- Limited for Stage IIIB lung adenocarcinoma
- Besides *EGFR* (LAURA trial), limited data for unresectable Stage I-III lung cancer

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**QUESTION 3**

Mr. Smith was diagnosed with resectable Stage IIIA lung adenocarcinoma that harbors an *EML4-ALK* fusion. PD-L1 was noted to be 90%. After resection, what systemic therapy should be considered?

1. Concurrent chemoradiation followed by durvalumab consolidation
2. Single agent pembrolizumab
3. Alectinib
4. Chemotherapy only

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**Back to the Medical Oncology Clinic**

**Discussion of results of surgical and interventional pulmonary evaluation**

- Noninvasive mediastinal staging confirmed metastatic disease to left hilar lymph node with no additional N2 Lymph node involvement – **Final clinical staging Stage IIIA- cT3cN1M0**
- Surgical evaluation: Appropriate for upfront surgical resection
- Moffitt STAR: ***EML4-ALK* fusion**

**Surgical resection**

- Robotic Left lower lobe lobectomy with mediastinal LN dissection with final pathology confirming Stage IIIA disease ( pT3pN1M0)

**Discussion of Adjuvant therapy**

- **Adjuvant alectinib for 24 months**

**Moffitt STAR Result**

Molecular Report Summary		
Genomic Alterations with Clinical Significance (see below for interpretation)		
FUSION VARIANT	BREAKPOINT	SUPPORTING READS
<i>EML4-ALK</i>	chr7:433285A_chr22:944839A	2907
Other Biomarkers		
BIOMARKER	LEVEL	VALUE
TMB	Low	0.8 mut/Mb
MSI	MS-Stable	0.2% Unstable Sites

Image courtesy of Moffitt Cancer Center

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### Role of Pharmacy

- **Pharmacist**
  - Review medication orders
  - Screen for drug-drug, drug-food, and drug-herb interactions
  - Provide patient counseling
- **Pharmacy Technician**
  - Medication authorization
  - Patient assistance
  - Coordination of care
  - Prescription processing
  - Medication ordering
  - Inventory



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### Pharmacy Patient Counseling - Alectinib

- **Administration/Handling**
- **Missed doses**
- **Common Adverse Effects**
  - Nausea/vomiting
  - Hepatotoxicity
  - Diarrhea
  - Anemia
- **Rare Adverse Effects**
  - Interstitial lung disease
  - Severe muscle pain



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### Nurse Navigator can Assist with Continuum of Care

- Help with appointments for follow-up imaging
- Additional appointments with Medical Oncologist
- Family and Medical Leave Act (FMLA) paperwork
- Any changes with insurance



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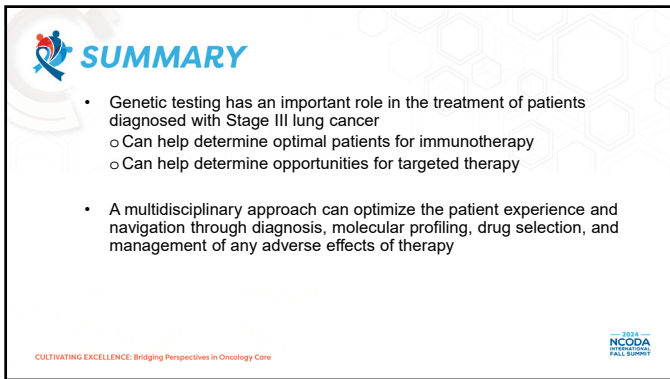
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**SUMMARY**

- Genetic testing has an important role in the treatment of patients diagnosed with Stage III lung cancer
  - Can help determine optimal patients for immunotherapy
  - Can help determine opportunities for targeted therapy
- A multidisciplinary approach can optimize the patient experience and navigation through diagnosis, molecular profiling, drug selection, and management of any adverse effects of therapy

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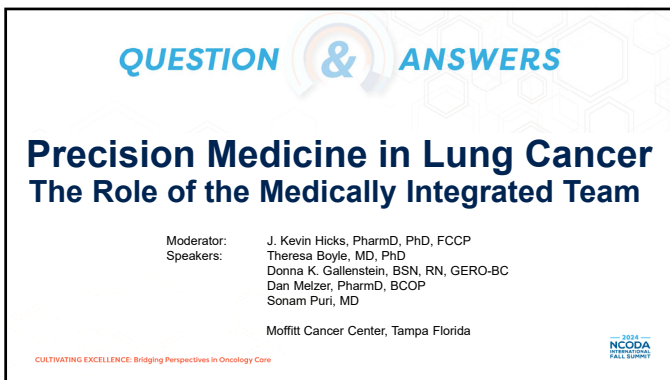
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**QUESTION & ANSWERS**

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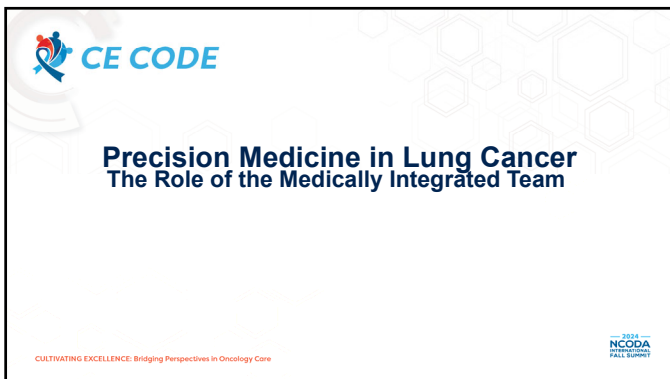
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**CE CODE**

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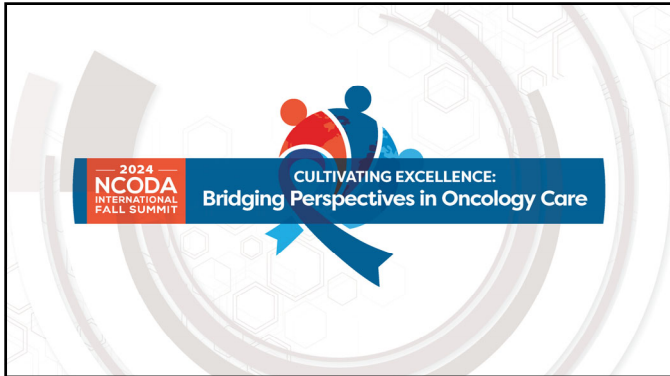
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