Lung Cancer Biomarker Testing ECHO
Case Presentation Form

Instructions
This case presentation form is intended to be completed and submitted electronically. Please email completed forms along with any optional supplemental information to korey.hofmann@cancer.org and carbon copy your regional ACS lead. We request that you submit your case presentation form **two weeks** prior to your scheduled case presentation. Please do NOT submit a scan of a printed version of this form.

This form includes four sections: **Section 1: Presenter Information & Case Presentation Summary**, **Section 2: System-Level Case Presentation**, **Section 3: Patient-Level Case Presentation** and **Section 4: Subject Matter Expert (SME) and Hub Team Recommendations**. You need to complete Section 1 and then, choose **either** Section 2 or Section 3. We recommend that each case presentation will range from **three minutes to five minutes**. Please do not include patient identifiers on this form or use any identifiers during the presentation. Please note, for patient-level case presentations, the SMEs and Hub Team will provide guidance that should NOT be interpreted as direct medical advice.

Project ECHO Data Usage Statement
Project ECHO® collects registration, participation, questions/answers, chat comments, and poll responses for some teleECHO® programs. Your individual data will be kept confidential. These data may be used for reports, maps, communications, surveys, quality assurance, evaluation, research, and to inform new initiatives.

Section 1: Presenter Information and Case Presentation Summary

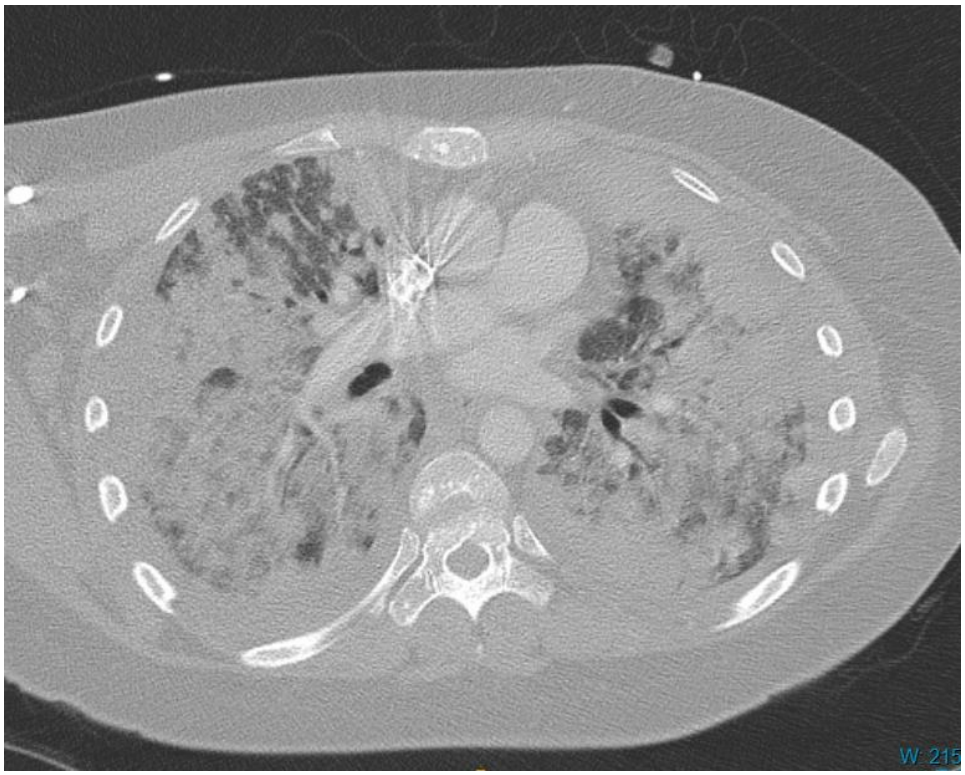
1. **Presentation Date:** 01/17/2024
2. **Presenter Name(s):** Mohamed K. Mohamed, MD, PhD
3. **Presenter Title(s):** Thoracic Medical Oncologist
4. **Organization/Health System:** Cone Health Cancer Center, Greensboro, NC.

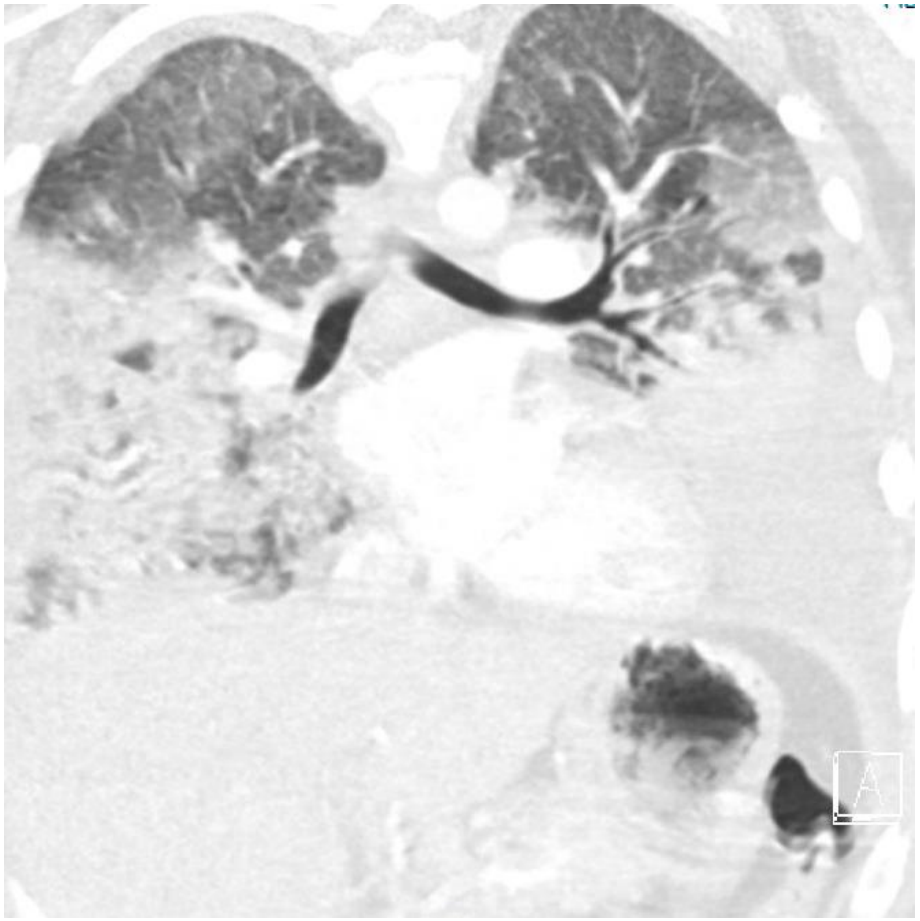
Please summarize the case you are presenting to the group: A never smoker 32 Year old female admitted to the hospital with worsening dyspnea and tachycardia started 3 months before. She was at urgent care centers and treated for allergy and asthma with no improvements. She was hypoxic with O2 sat of 86% on 6 L of Oxygen and Face mask. CT angiogram of the chest was read as extensive peripheral predominant areas of patchy consolidation throughout both lungs, likely representing multifocal pneumonia with likely reactive subcentimeter mediastinal and hilar nodes. Bronchoscopy was performed and the pathology was consistent with poorly differentiated carcinoma with signet ring features positive for CK7 and TTF-1 (lung primary). Molecular studies by NGS blood test was negative but the tissue biopsy NGS result was positive for ALK-EML4 fusion.

She started immediately on treatment with Alectinib and has improvement in few days and discharged home with no O2 requirements.

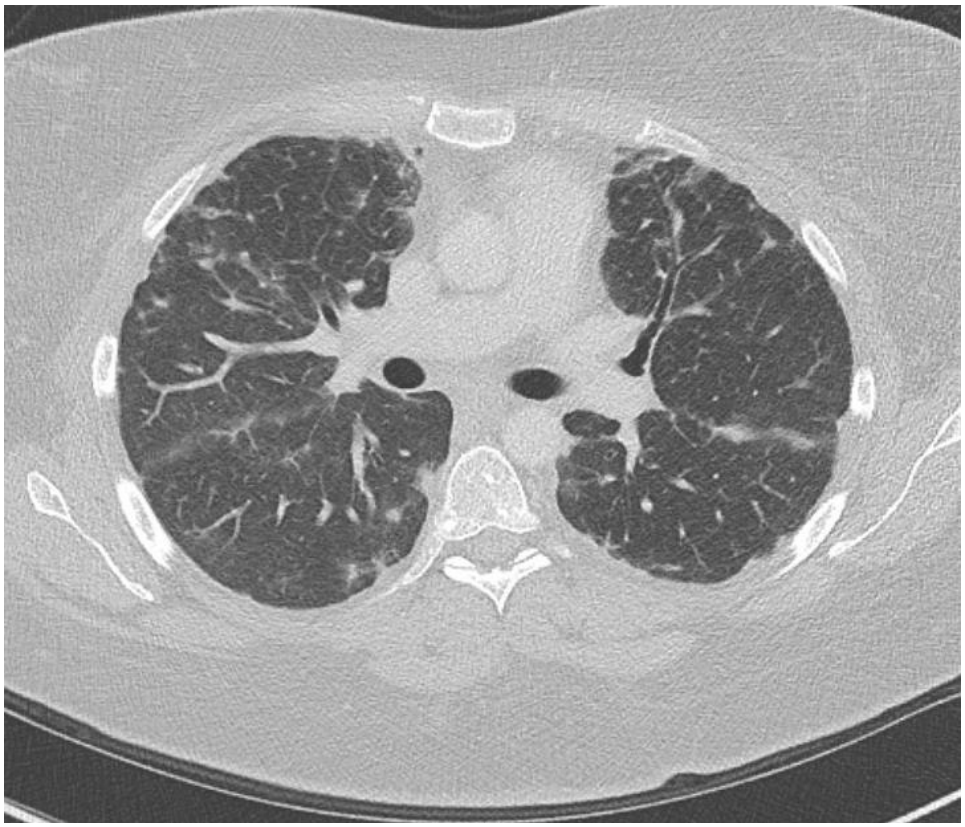
5. **Which specific questions are you asking the Hub Team and the other participant learning sites?**
   - **a)** How accurate is liquid biopsy for identification of ALK and other fusion protein abnormalities?
   - **b)** How can we improve the turnaround time for NGS tissue biopsy results?
   - **c)** Should we adopt the concurrent liquid and tissue NGS testing?

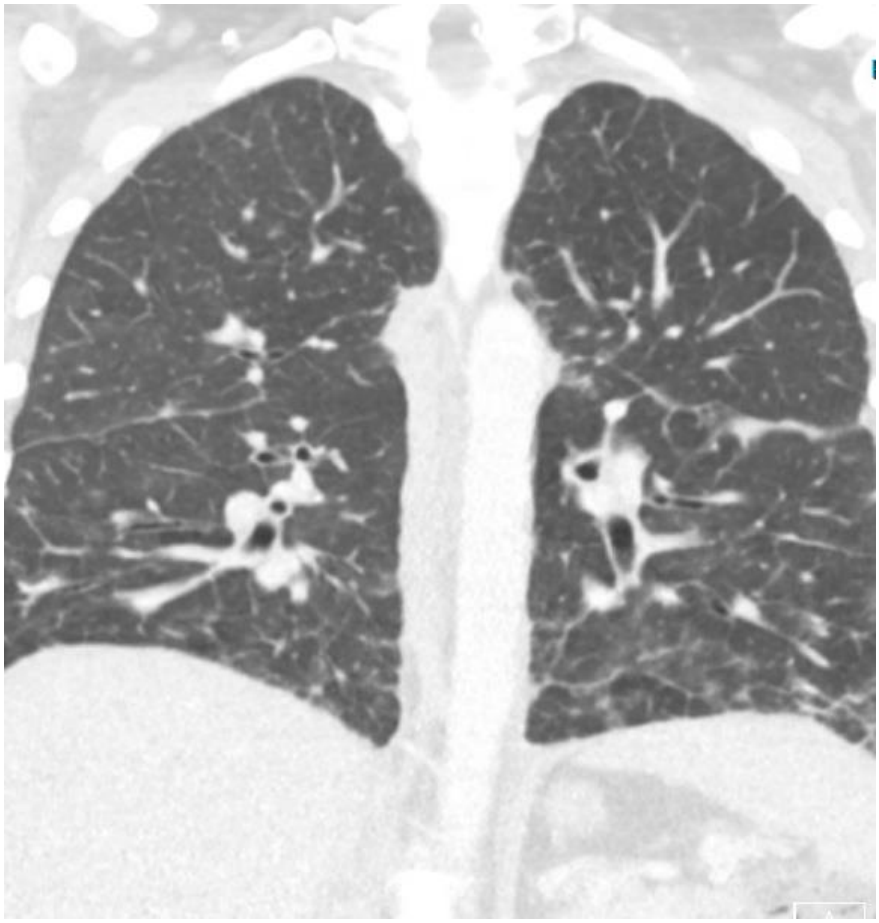
32 YOF with stage IV NSCLC, Adenocarcinoma and ALK Gene Translocation at presentation





32 YOF with stage IV NSCLC, Adenocarcinoma and ALK Gene Translocation 6 wks. after Alectinib treatment





Section 2: System-Level Case Presentation

1. **Describe your current system or workflow:** *If available, feel free to provide workflow charts separately.*
   We currently send concurrent liquid and tissue for NGS testing at the time of Bronchoscopy.
2. **What are the primary challenges/barriers:** *Include specifics on identified gaps and quality improvement methods used to clarify the root causes*.
   a) Insufficient material is still an issue especially from biopsy of small lesions.
   b) Turnaround time for tissue biopsy NGS testing.

3. **Describe what you are trying to improve and any other relevant background information:**
   a) Working with the interventionist to obtain more materials for testing
   b) Working with pathologists to save tissue from extensive and sometimes unnecessarily IHC.
   c) Sending Concurrent liquid and tissue biopsy for NGS testing.

4. **Briefly describe your vision of what it will look like when it is working well:**
   Multidisciplinary approach to patients with cancer and all the team member working for one goal, Good patient care.

5. **Describe any recent changes (less than 6 months) made to this system or workflow, including when they were made and their impact:**
   As Above.

6. **If applicable, what data (quantitative, qualitative) do you have to augment your observations:**
   None

Section 3: Patient-Level Case Presentation

<table>
<tr><td colspan="5">DEMOGRAPHIC INFORMATION</td></tr>
<tr><td>1. Age</td><td colspan="2">2. Gender (Choose One)</td><td colspan="2">3. Race/Ethnicity (Choose All that Apply)</td></tr>
<tr><td>32</td><td colspan="2">Female X☐
Male☐
Non-Binary/Third gender☐
Transgender female☐
Transgender male ☐</td><td>American Indian/Alaska Native ☐
Asian ☐
Black/African American ☐</td><td>Hispanic/Latino ☐
White X☐
More than One Race ☐
Other ☐</td></tr>
<tr><td colspan="5">NON-SMALL CELL LUNG CANCER (NSCLC) HISTOLOGY & STAGE</td></tr>
<tr><td>4. Diagnosis</td><td>5. Histology</td><td colspan="3">6. Stage</td></tr>
<tr><td>Initial Diagnosis ☐X
Recurred and or Progressed ☐</td><td>Adenocarcinoma X
☐ Squamous Cell
☐ Large Cell ☐</td><td colspan="3">Stage IV</td></tr>
<tr><td colspan="5">BIOMARKER TESTING</td></tr>
<tr><td colspan="2">7. Has biomarker testing been ordered for this patient (or will it be ordered)?</td><td colspan="3">8. If biomarker testing was not ordered, please elaborate on the factors that precluded it:</td></tr>
<tr><td colspan="2">Yes X☐
No ☐
Will be ordered ☐</td><td colspan="3">Click or tap here to enter text.</td></tr>
<tr><td colspan="5">The next section is ONLY for those patients who HAVE received or WILL receive biomarker testing</td></tr>
<tr><td colspan="5">9. Which technique was used (or will be used) to obtain specimen for pathologic diagnosis? (Choose One)</td></tr>
<tr><td colspan="2">Bronchoscopic biopsy X ☐
Endobronchial ultrasound-guided transbronchial lymph node aspiration (EBUS-TBNA) ☐
Image-guided percutaneous biopsy ☐
Liquid biopsy X☐</td><td colspan="3">Mediastinoscopy ☐
Surgical specimen ☐
Thoracentesis/pericardiocentesis ☐
Unsure ☐</td></tr>
<tr><td colspan="2">10. Which platform was/will be used for lung biomarker testing? (Choose One)</td><td colspan="3">11. If single-gene test or short-cluster panel, please identify which genes were tested:</td></tr>
<tr><td colspan="2">Single-Gene Test ☐
Short-Cluster Panel ☐
Multi-Gene Panel (next generation sequencing (NGS) X☐</td><td>ALK ☐
BRAF ☐
EGFR ☐</td><td>HER2 ☐
KRAS ☐
NTRK ☐
MET ☐</td><td>PD-L1 ☐
ROS1 ☐
RET ☐</td></tr>
<tr><td colspan="5">ADDITIONAL INFORMATION</td></tr>
<tr><td colspan="5">12. Please include any other information you would like to share with the group:
Positive ALK EML4.</td></tr>
</table>

Section 4: Subject Matter Expert and/or Hub Team Recommendations

This section will be completed by the ACS ECHO Coordinator. Recommendations from our Hub Team will be documented below.

a) How accurate is liquid biopsy for identification of ALK and other fusion protein abnormalities?
b) How can we improve the turnaround time for NGS tissue biopsy results?
c) Should we adopt the concurrent liquid and tissue NGS testing?

Highlights from Case Discussion

Should we adopt the concurrent liquid and tissue NGS testing? How do others approach this?
Dr. Mohammed works with pulmonologists to send liquid and tissue NGS test from bronchoscopy suite.

Question referring back to didactic presentation on how the group approaches insurance coverage for testing when patient is treated inpatient and how does the group work around the CMS 14-day rule? Do you wait until after 14 days after hospitalization for the test to be covered or advocate for the need for immediate testing and risk financial toxicity for the hospital. (CMS patients 14-day rule – inpatient vs outpatient)

Dr. Mohamed– Not currently running into an issue getting coverage for testing, even if patient is inpatient; outpatient 14-day rule was eliminated in 2022

Dr. Fox – Suggested that making an appeal to the insurer that the test is not for inpatient treatment so the 14-day rule shouldn't be applied. (this advice was offered to Dr. Fox by a CMS contractor) At MUSC, often hospital will conduct tests in-house and will absorb the cost of testing to expedite results for treatment decision-making.

Does hospital have molecular or thoracic tumor board to help influence insurance coverage for patients who need it?

Dr. Mohamed – Molecular/thoracic tumor board doesn't have that much power to influence CMS rules to ensure coverage for biomarker testing. Feels that ASCO, ACS, etc. large organizations would have more influence on insurance coverage

Dr. Mullett – Commission on Cancer chose to work at a state level to advance legislation for coverage instead of advocating for a national policy for biomarker testing coverage.

Any thoughts on PD-L1 and blood-based testing? Is anyone using a blood-based PDL-1 test from Circulogene?

Dr. Mullett - Reflex-testing is a great opportunity for looking at PD-L1. It needs to be included for most of these cases.

Dr. Desai – Research ongoing, but not aware of a commercially available test and not familiar with Circulogene assay

Participant – We also need PD-L1 for clinicial trials eligibility status. Right now we start with pathologists for in-house testing, but that is not ideal for just one assay.

Section 4: Subject Matter Expert and/or Hub Team Recommendations

Assigned Case Presentation Number: Will be assigned by ACS