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MULTIDISCIPLINARY APPROACHES TO CANCER SYMPOSIUM

Non-Small-Cell Lung Cancer (NSCLC) Tumor Board

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- *Stock/Shareholder in January Therapeutics*

This presentation and/or comments will be free of any bias toward or promotion of the above referenced company or their product(s) and/or other business interests.

This presentation and/or comments will provide a balanced, non-promotional, and evidence-based approach to all diagnostic, therapeutic and/or research related content.

This presentation has been peer-reviewed and no conflicts were noted.

Cultural Linguistic Competency (CLC) & Implicit Bias (IB)

STATE LAW:

The California legislature has passed Assembly Bill (AB) 1195, which states that as of July 1, 2006, all Category 1 CME activities that relate to patient care must include a cultural diversity/linguistics component. It has also passed AB 241, which states that as of January 1, 2022, all continuing education courses for a physician and surgeon **must** contain curriculum that includes specified instruction in the understanding of implicit bias in medical treatment.

The cultural and linguistic competency (CLC) and implicit bias (IB) definitions reiterate how patients' diverse backgrounds may impact their access to care.

EXEMPTION:

Business and Professions Code 2190.1 exempts activities which are dedicated solely to research or other issues that do not contain a direct patient care component.

The following CLC & IB components will be addressed in this presentation:

- Differences and similarities in outcomes amongst different populations
- What are some groups who frequently experience disparities in care

NSCLC Tumor Board Agenda

- Introduction
- Case #1: Neoadjuvant therapy
- Case #2: Adjuvant therapy
- Case #3: Definitive chemoradiation
- Case #4: Oligometastatic disease

Lung Cancer Incidence and Mortality

Estimated New Cases

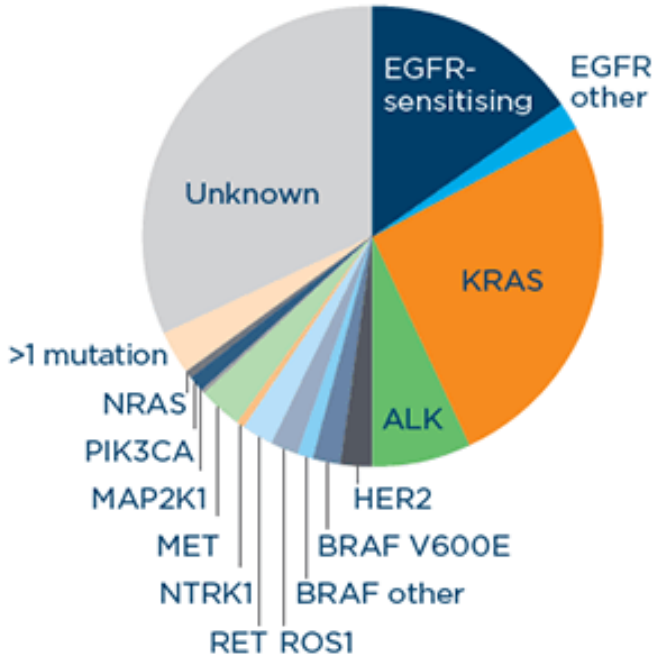
Males			Females		
Prostate	268,490	27%	Breast	287,850	31%
Lung & bronchus	117,910	12%	Lung & bronchus	118,830	13%
Colon & rectum	80,690	8%	Colon & rectum	70,340	8%
Urinary bladder	61,700	6%	Uterine corpus	65,950	7%
Melanoma of the skin	57,180	6%	Melanoma of the skin	42,600	5%
Kidney & renal pelvis	50,290	5%	Non-Hodgkin lymphoma	36,350	4%
Non-Hodgkin lymphoma	44,120	4%	Thyroid	31,940	3%
Oral cavity & pharynx	38,700	4%	Pancreas	29,240	3%
Leukemia	35,810	4%	Kidney & renal pelvis	28,710	3%
Pancreas	32,970	3%	Leukemia	24,840	3%
All Sites	**983,160**	**100%**	**All Sites**	**934,870**	**100%**

Estimated Deaths

Males			Females		
Lung & bronchus	68,820	21%	Lung & bronchus	61,360	21%
Prostate	34,500	11%	Breast	43,250	15%
Colon & rectum	28,400	9%	Colon & rectum	24,180	8%
Pancreas	25,970	8%	Pancreas	23,860	8%
Liver & intrahepatic bile duct	20,420	6%	Ovary	12,810	4%
Leukemia	14,020	4%	Uterine corpus	12,550	4%
Esophagus	13,250	4%	Liver & intrahepatic bile duct	10,100	4%
Urinary bladder	12,120	4%	Leukemia	9,980	3%
Non-Hodgkin lymphoma	11,700	4%	Non-Hodgkin lymphoma	8,550	3%
Brain & other nervous system	10,710	3%	Brain & other nervous system	7,570	3%
All Sites	**322,090**	**100%**	**All Sites**	**287,270**	**100%**

Mutations in NSCLC

DRIVER MUTATIONS IN LUNG ADENOCARCINOMA



Driver mutations in lung adenocarcinoma	
EGFR-sensitizing	15%
EGFR other	2%
KRAS	25%
ALK	7%
HER2	2%
BRAF V600E	2%
BRAF other	1%
ROS1	2%
RET	2%
NTRK1	0–5%
MET	3%
MAP2K1	0–5%
PIK3CA	1%
NRAS	0–5%
>1 mutation	3%
Unknown	31%

***EGFR* sensitizing**
Gefitinib; Erlotinib; Afatinib; Osimertinib; Dacomitinib

ALK
Crizotinib; Alectinib; Ceritinib; Lorlatinib; Brigatinib

ROS1
Crizotinib; Cabozantinib; Ceritinib; Lorlatinib; Entrectinib; Ropotrectinib, DS-6051b

BRAF
Vemurafenib, Dabrafenib; Dabrafenib + Trametinib

NTRK1
Entrectinib; Larotrectinib; loxo-195; DS-6051b; repotrectinib

HER2
Trastuzumab emtansine; Afatinib; Neratinib-temsirolimus; Dacomitinib; Poziotinib; XMT-1522; TAK-788; DS-8201a

RET
Selpercatinib; Cabozantinib; Apatinib; Vandetanib; Ponatinib; Lenvatinib; BLU-667

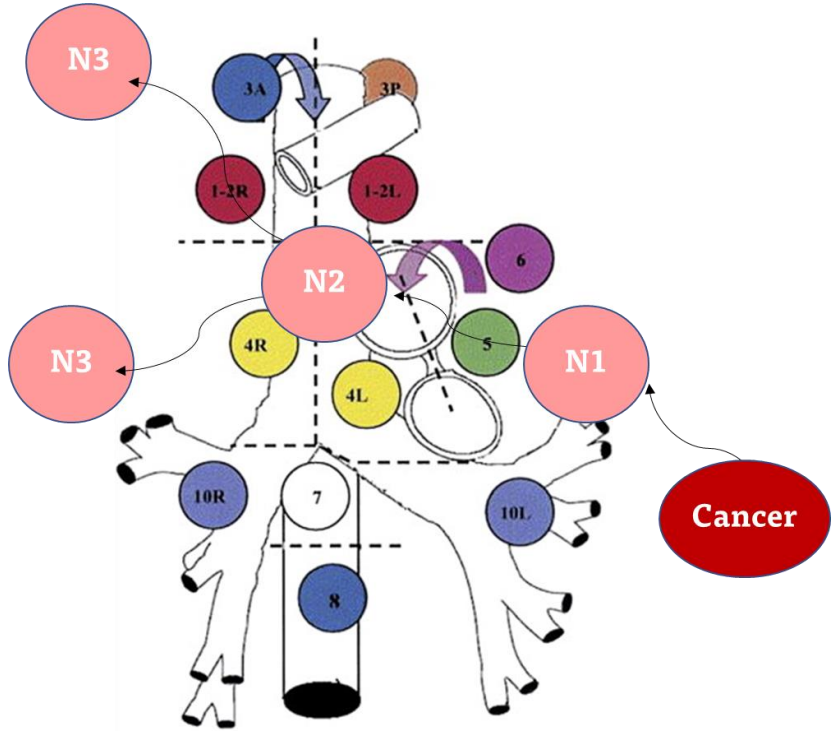
MET
Crizotinib; Cabozantinib; Capmatinib; Savolitinib; Tepotinib; Merestinib; Glesatinib

KRAS
Sotorasib

MEK1
Trametinib; Selumetinib; Cobimetinib

Staging

T (Primary Tumor)	
T0	No primary tumor
Tis	Carcinoma in situ (Squamous or Adenocarcinoma)
T1	Tumor ≤3 cm,
T1a(mi)	Minimally Invasive Adenocarcinoma
T1a	Superficial spreading tumor in central airways[a]
T1a	Tumor ≤1 cm
T1b	Tumor >1 but ≤2 cm
T1c	Tumor >2 but ≤3 cm
T2	Tumor >3 but ≤5 cm or tumor involving: visceral pleura[b], main bronchus (not carina), atelectasis to hilum[b]
T2a	Tumor >3 but ≤4 cm
T2b	Tumor >4 but ≤5 cm
T3	Tumor >5 but ≤7 cm or invading chest wall, pericardium, phrenic nerve or separate tumor nodule(s) in the same lobe
T4	Tumor >7 cm or tumor invading: mediastinum, diaphragm, heart, great vessels, recurrent laryngeal nerve, carina, trachea, esophagus, spine; or tumor nodule(s) in a different ipsilateral lobe



N (Regional Lymph Nodes)	
N0	No regional node metastasis
N1	Metastasis in ipsilateral pulmonary or hilar nodes
N2	Metastasis in ipsilateral mediastinal/subcarinal nodes
N3	Metastasis in contralateral mediastinal/hilar, or supraclavicular nodes

M (Distant Metastasis)	
M0	No distant metastasis
M1a	Malignant pleural/pericardial effusion[c] or pleural /pericardial nodules or separate tumor nodule(s) in a contralateral lobe;
M1b	Single extrathoracic metastasis
M1c	Multiple extrathoracic metastases (1 or >1 organ)

Treatment Approvals in Resectable NSCLC with and without Driver Mutations

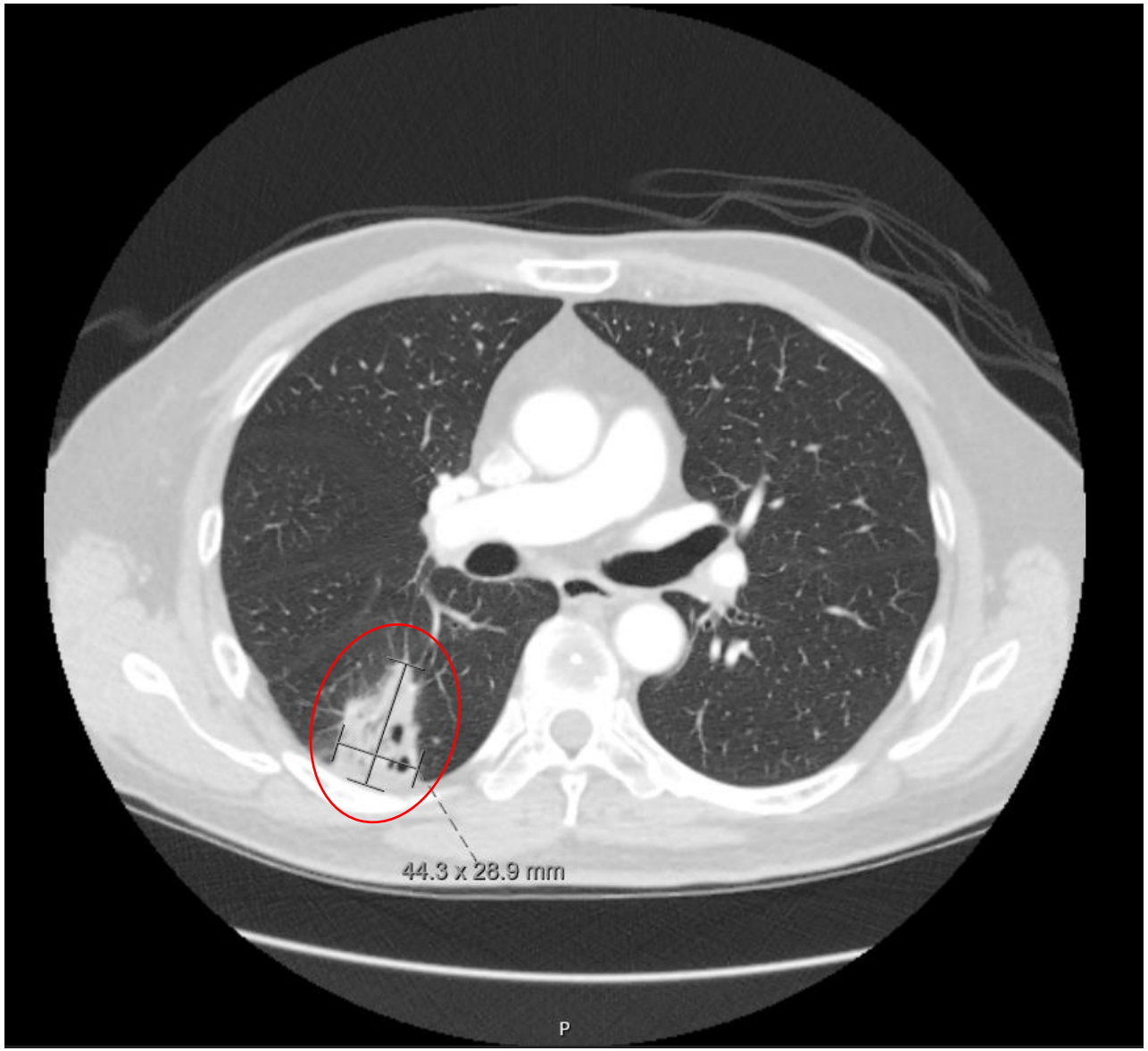
With Driver Mutations

Without Driver Mutations

Case #1: Neoadjuvant Therapy

Case #1: Presentation

- 63-year-old male, former smoker with 15 pack-year history, was found to have a **right lower lobe consolidation**.
- Further work with a **CT chest** showed a 4.7 cm **right lower lobe mass** with no mediastinal lymphadenopathy.


44.3 x 28.9 mm
P

Case #1: Work-up

- He then underwent a PET/CT demonstrating a **4.4 cm hypermetabolic mass**. There was no hilar or mediastinal lymphadenopathy. There was a mildly hyperbolic neck lymph node most consistent with inflammatory process. There was also a 15 x 7 mm right adrenal nodule without metabolic activity thought to be benign.
- A CT-guided needle biopsy of the hypermetabolic mass revealed **mucinous adenocarcinoma**.
- EBUS with biopsy of the station 4R and 7 were negative for malignant cells.
- Final clinical staging was stage IIA, cT2bN0M0.
- Genomic testing revealed a **SLC3A2-NRG1 Fusion** and **MSI stable**.

Case #1: Presentation Summary

- 63-year-old male with 15 pack-years smoking history with newly diagnosed right lower lobe mucinous adenocarcinoma that appears to be stage IIA, T2bN0M0.
- Given the work-up thus far, what would you recommend for this patient?

Result
HopeSeq Solid Tumors Comprehensive

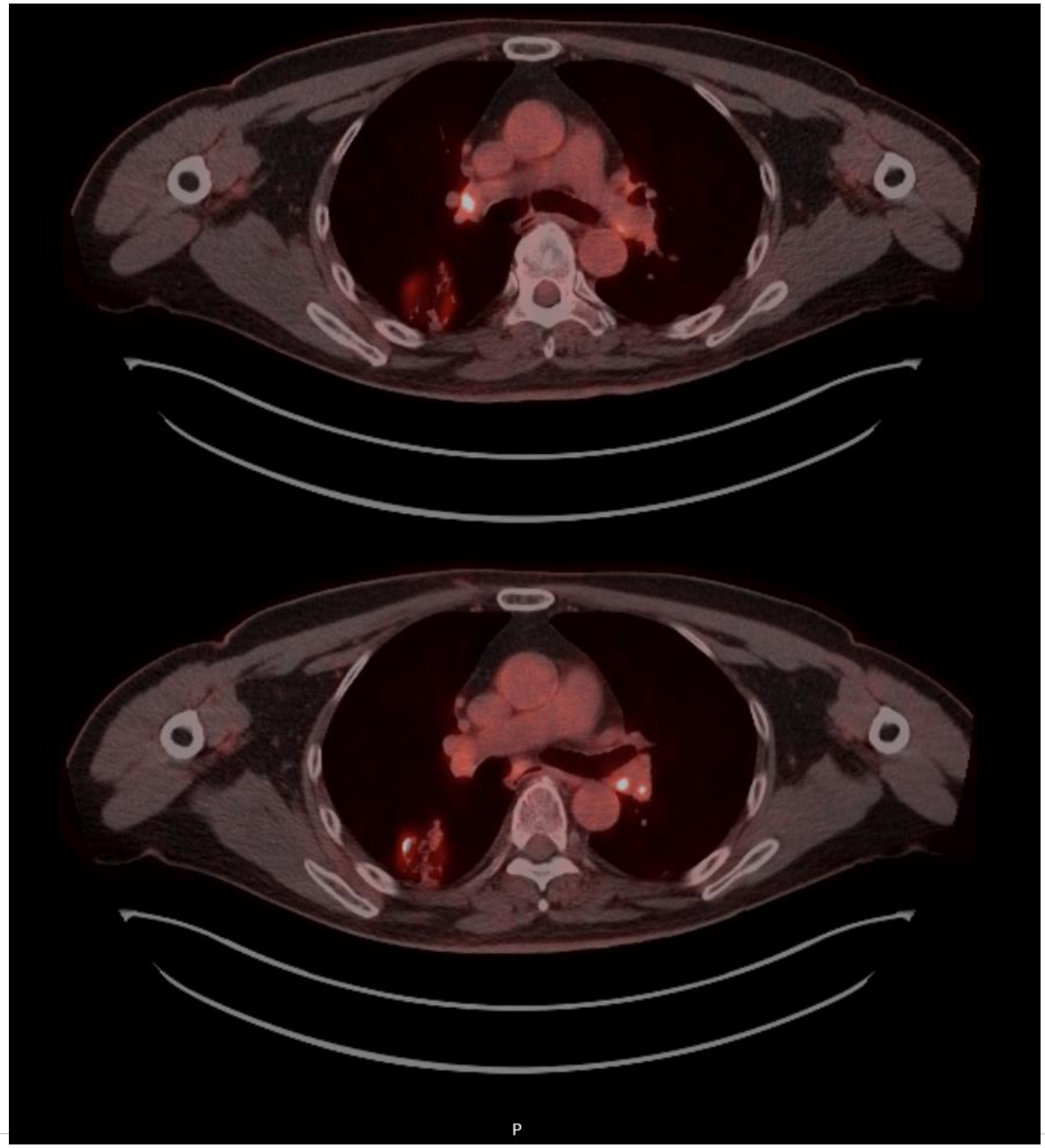
Genomic Alterations Detected	Allele Frequency	FDA-Approved Therapies in patient's tumor*	FDA-Approved Therapies in other tumor type*
SLC3A2-NRG1 Fusion	N/A	None	None

TUMOR MUTATIONAL BURDEN STATUS (TMB)
Low

MICROSATELLITE STATUS (MSI)
Stable

Case #1: Treatment

- Patient was recommended for neoadjuvant chemotherapy plus immunotherapy with 3 cycles of **cisplatin, pemetrexed, and nivolumab** before surgery based on evidence from trials such as CheckMate 816 and NADIM.
- MRI Brain showed absence of metastases. Post-treatment PET/CT demonstrated overall decrease in the RLL mass, but several FDG avid bilateral **cervical**, **mediastinal**, and **hilar nodes** suspicious for metastatic adenopathy.
- Patient underwent ultrasound-guided biopsy of the **left cervical lymph node**, which was negative for malignant cells.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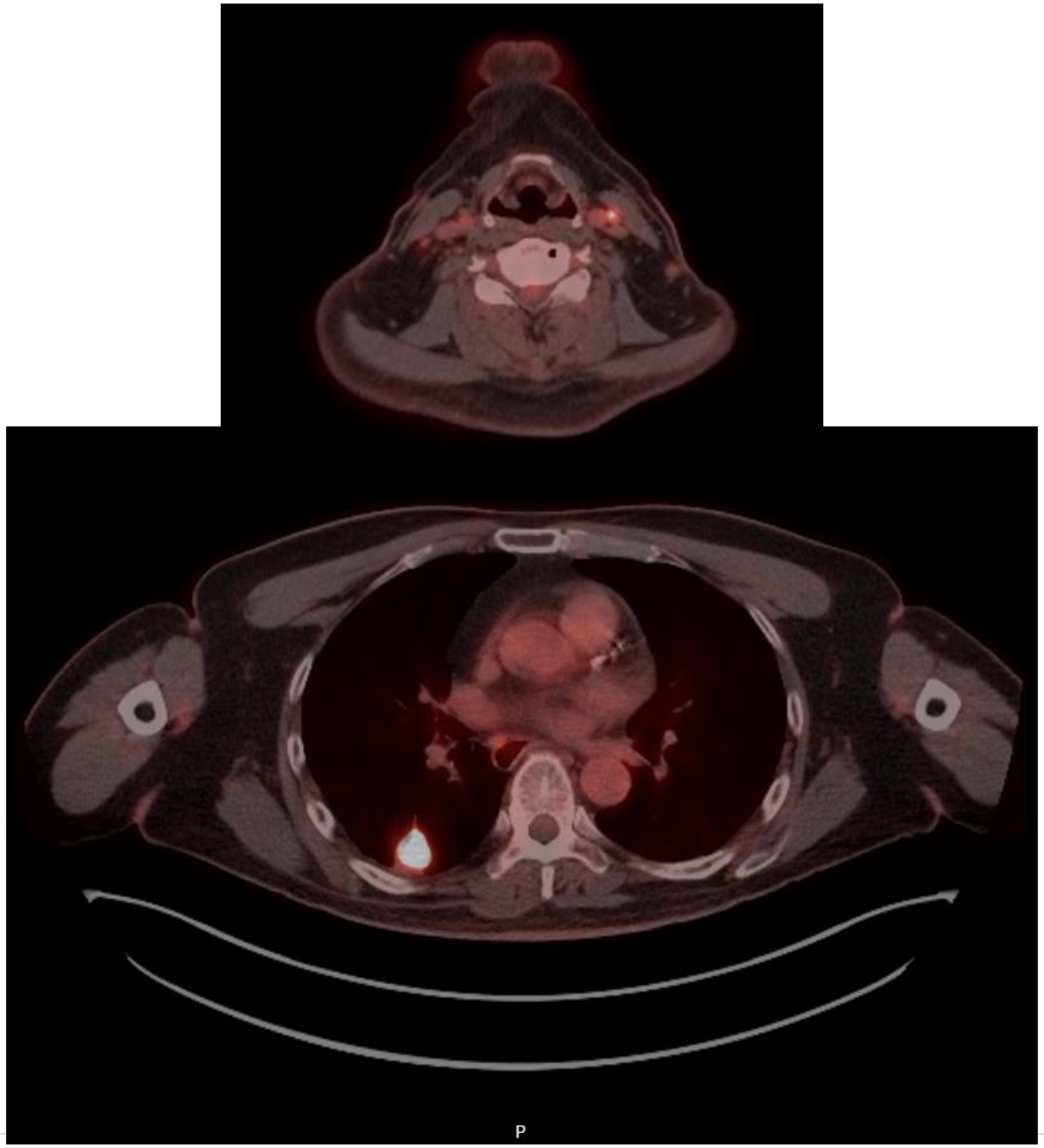
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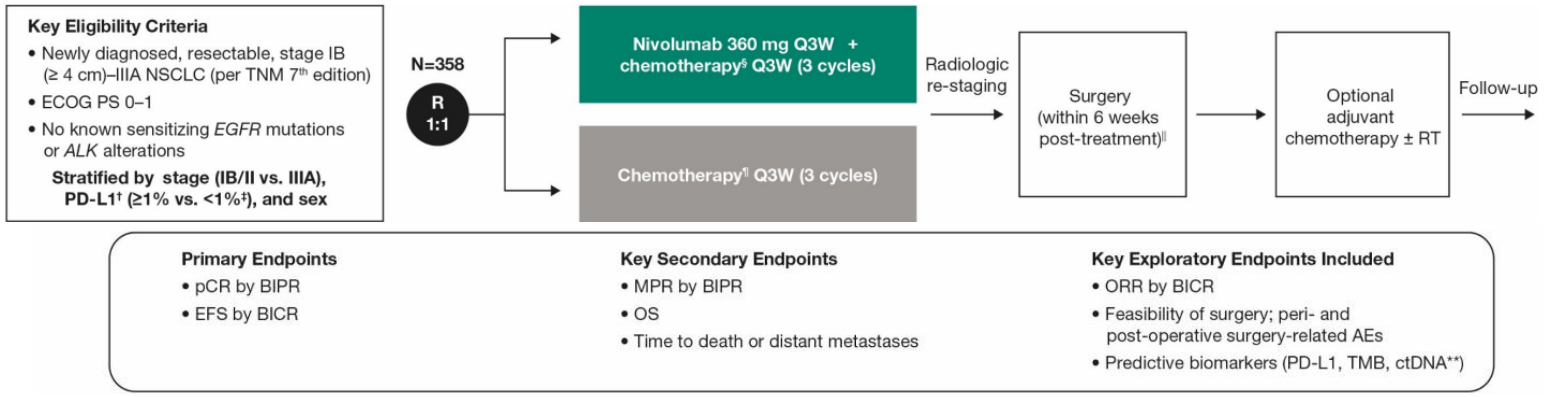
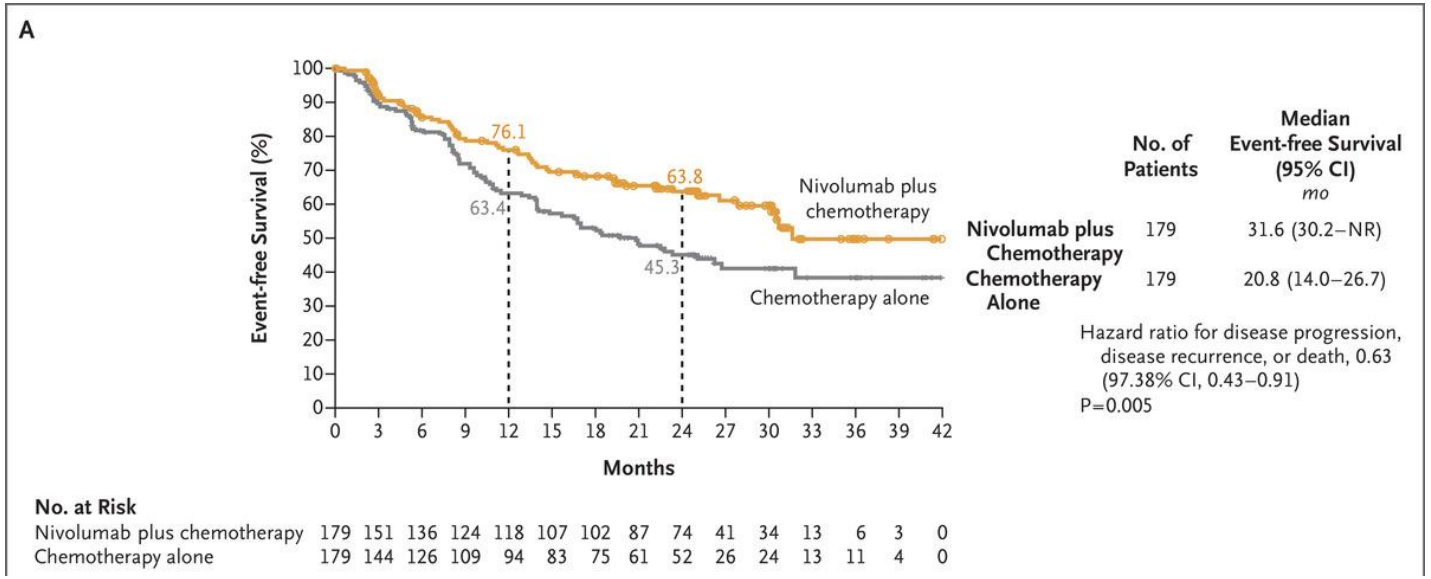
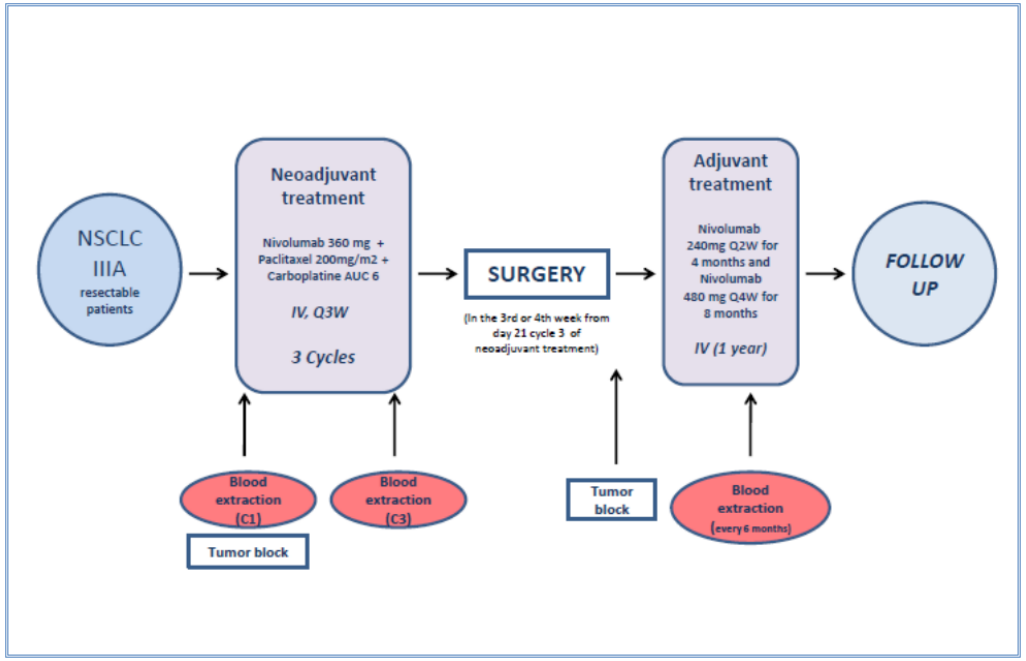
CheckMate 816: Neoadjuvant Nivo + Platinum-Doublet Chemotherapy in Resectable (IB-IIIA) NSCLC

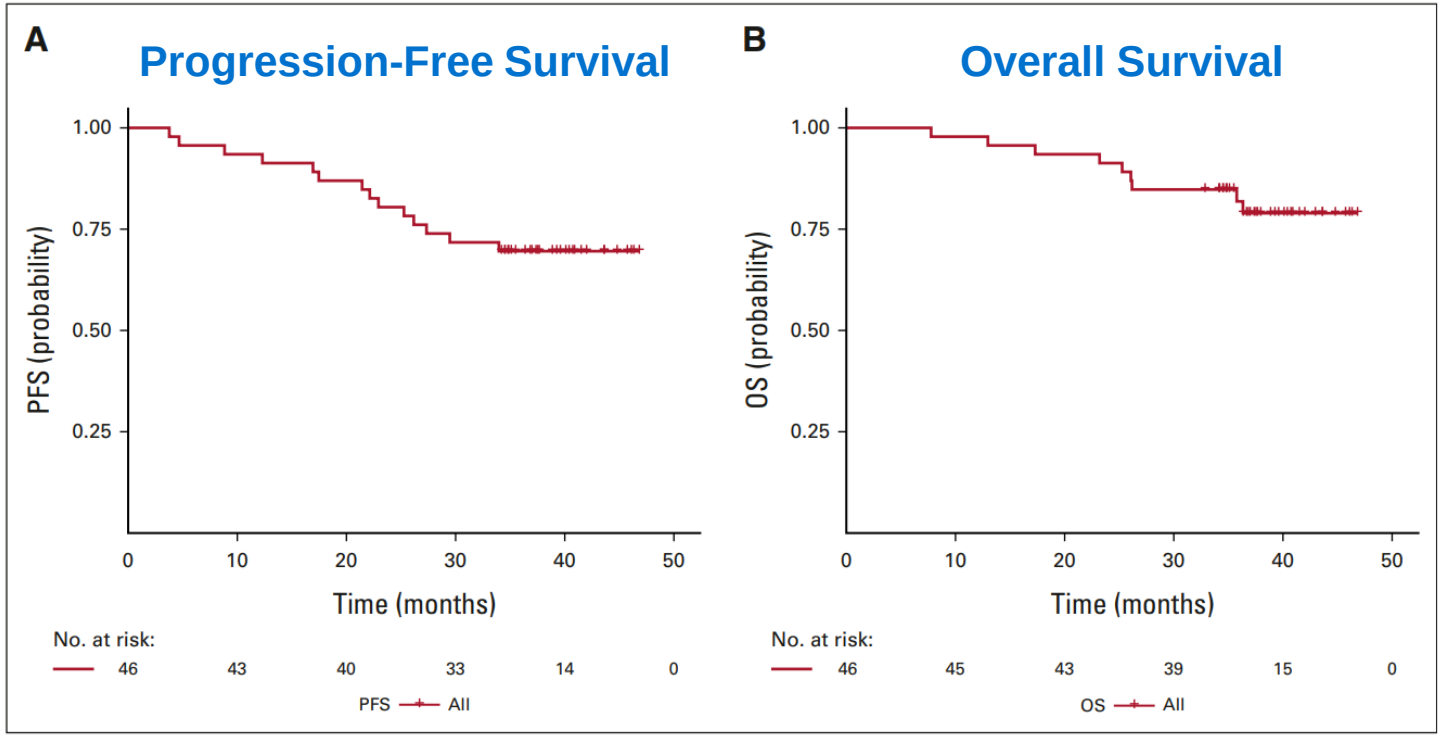




Forde PM et al. NEJM 2022

NADIM: Neoadjuvant Nivolumab Plus Chemotherapy in Operable Stage IIIA NSCLC





Case #1: Treatment

- He then presented to clinic with **fatigue**, **nausea**, **vomiting** and possible **adrenal insufficiency** likely secondary to immunotherapy.
- Our endocrinology team stabilized the patient, and he was discharged.
- Patient will undergo a **robotic assisted right lower lobectomy** and **mediastinal lymph node dissection**.

Case #1: Treatment Summary & Next Steps

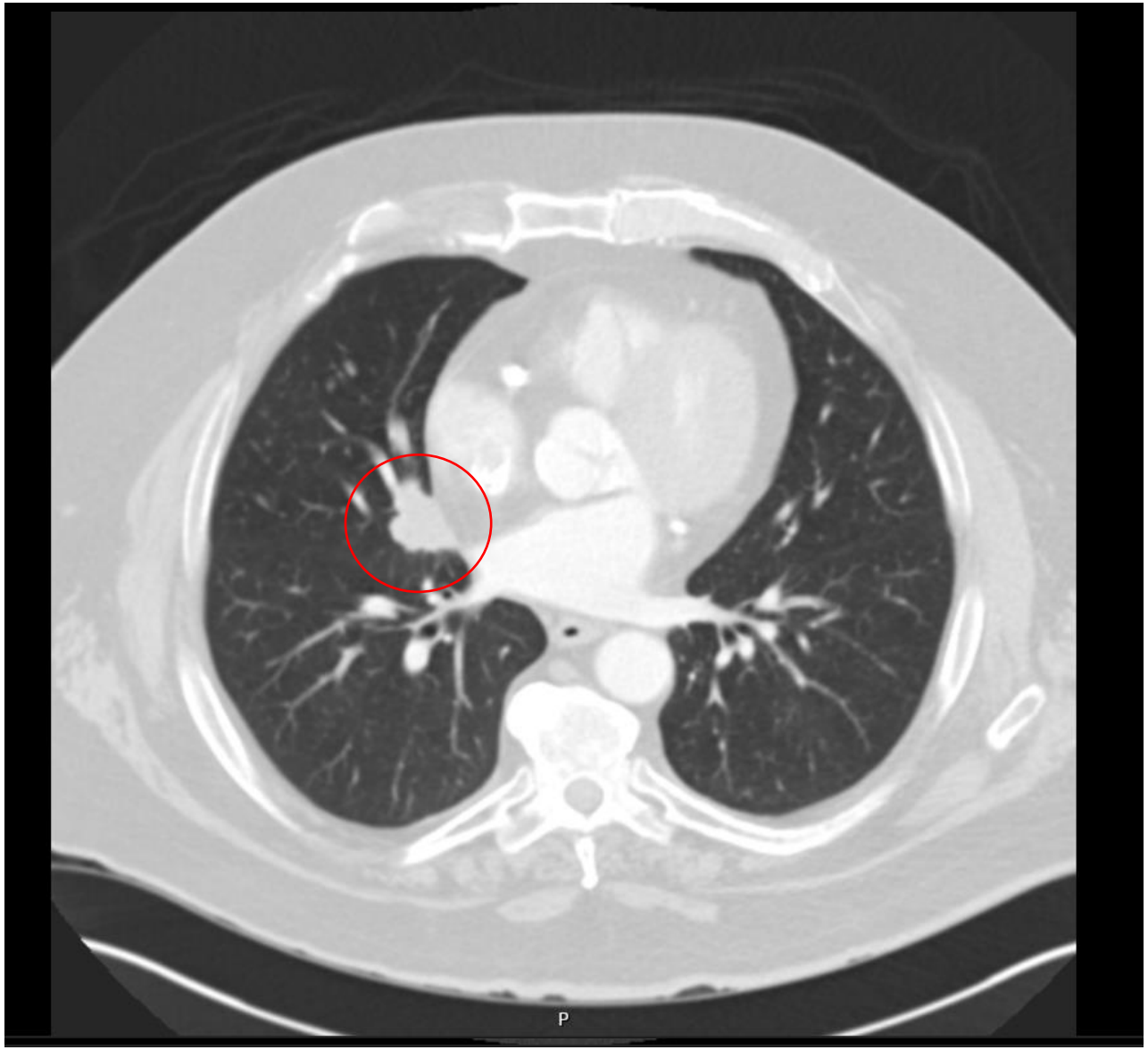
- Patient completed neoadjuvant chemotherapy plus immunotherapy with 3 cycles of **cisplatin, pemetrexed, and nivolumab** before surgery.
- Patient will undergo **robotic assisted right lower lobectomy** and **mediastinal lymph node dissection**.
- Recommendation: Follow-up.

Case #2: Adjuvant Therapy

Case #2: Presentation

- 75-year-old male, former smoker with 80 pack-year history and a past medical history of COPD, obesity, diabetes mellitus, and coronary artery disease, presented to the emergency room with chest pain.

- Further work with a **CTA chest** revealed a 2 x 3 cm right middle lobe mass. There was no mediastinal or hilar lymphadenopathy.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Case #2: Work-up

- He then underwent a PET/CT demonstrating a right middle lobe centrally-located **nodule** near right hilum, measuring **3.1 x 2.1 cm** with intense metabolic activity (SUVmax 12) and no FDG avid lymphadenopathy.
- A robotic bronchoscopic fine need biopsy was performed on the middle lobe nodule and revealed malignant cells present, consistent with **squamous cell carcinoma**.
- A repeat PET/CT scan did not show any mediastinal uptake but possibly showed some hilar uptake without anatomic correlate.
- Final clinical staging was stage IB, cT2aN0M0.

Case #2: Presentation Summary

- 75-year-old male with 80 pack-years smoking history and several comorbidities with newly diagnosed squamous cell carcinoma that appears to be stage IB, cT2aN0M0.
- Given the work-up thus far, what would you recommend for this patient?

Case #2: Treatment

- Patient under robotic-assisted right middle lobectomy and thorascopic wedge resection of right upper lobe and right lower lobe. He also underwent a mediastinal lymph node dissection during the surgery.

- Pathology demonstrated **squamous cell carcinoma**, moderately to poorly differentiated, measuring 4.2 cm grossly. Margins were uninvolved and no lymphovascular invasion was identified. All lymph nodes were negative for malignancy. Stage IIA, pT2bN0M0.

- NGS testing revealed a **TP53 R158P** mutation, **TMB low**, **MSI stable**, and **PD-L1 TPS 10%**.

Result
HopeSeq Lung

Genomic Sequencing Findings	Allele Frequency	FDA-Approved Therapies in patient's tumor*	FDA-Approved Therapies in other tumor type*
TP53 (c.473G>C, **p.R158P**)	**54%**	**None**	**None**
TUMOR MUTATIONAL BURDEN STATUS (TMB)			
Low			
MICROSATELLITE STATUS (MSI)			
Stable			
PD-L1 22C3 FDA (KEYTRUDA) for NSCLC STATUS			
Expressed			
Tumor Proportion Score: 10%			
Intensity: 1+			
Testing for PD-L1 was performed at NeoGenomics. The complete reference laboratory report is attached as an image at the end of this report.			

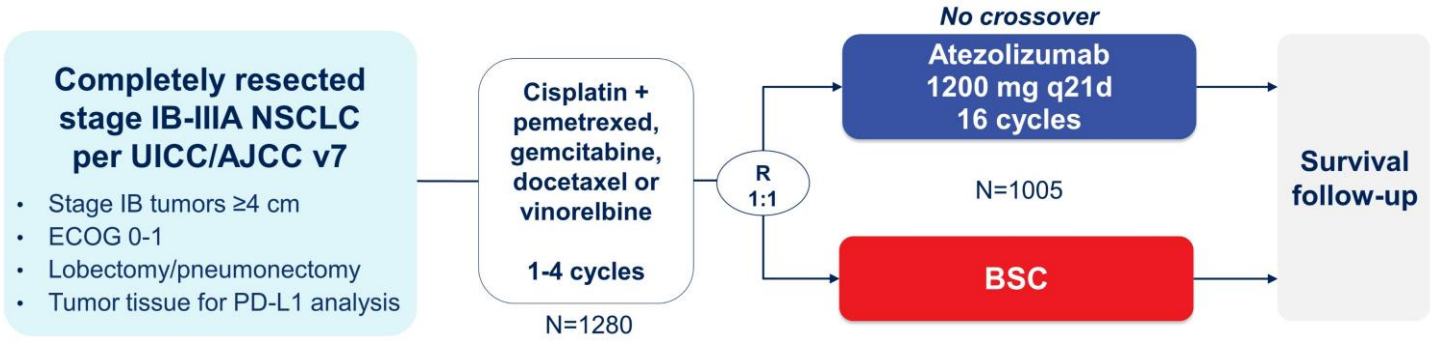
*Treatment decisions are the responsibility of the physician. Drugs referenced in this report are for informational purposes based on current knowledge and are not intended to be comprehensive of all treatment options. Drugs listed may not necessarily be suitable for a given patient. Treatment decisions should be based on the independent medical judgment of the physician and should also consider all other clinical information on the patient.

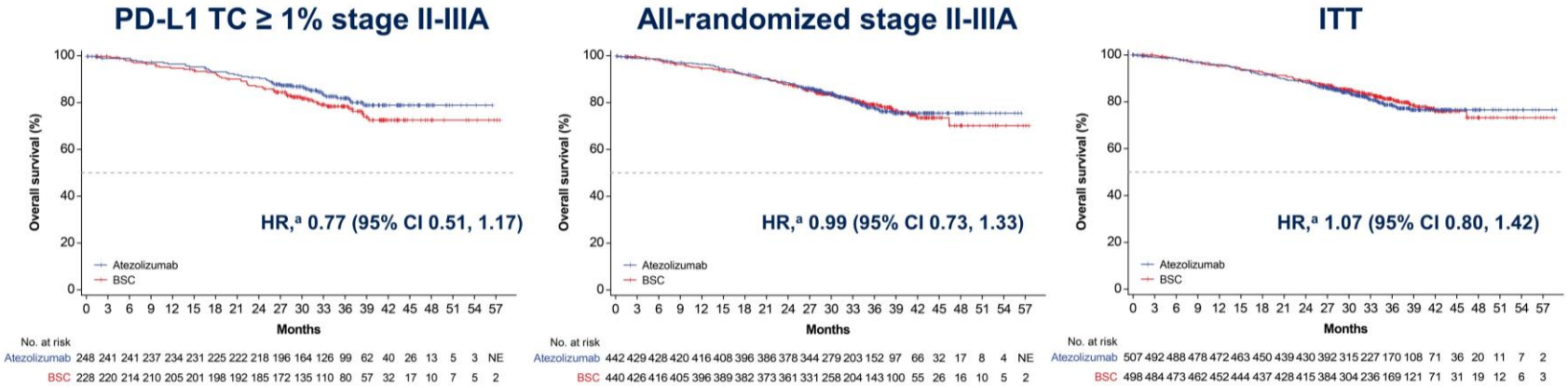
No other alterations of potential clinical significance including *EGFR*, *KRAS*, *ALK*, *BRAF*, *RET*, *ERBB2*, *ROS1*, and *MET* Exon 14 alterations were detected in the remaining targets of this assay.

Case #2: Treatment

- Considering **stage IIA** disease, there is indication for adjuvant chemotherapy followed by adjuvant atezolizumab for a 1-year duration (IMpower010).
- Patient declined chemotherapy and was started on **adjuvant atezolizumab**.
- Restaging PET/CT demonstrated new moderate **right pleural effusion** and **adjacent consolidation**. There was a slight increased size of borderline mediastinal lymph nodes which may be reactive.
- Recommendation was to follow-up with another **CT chest** in 3 months, which showed improving mild to moderate right pleural effusion, and stable mediastinal and right hilar nodes.

IMpower010: Adjuvant Atezolizumab in Completely Resected Stage IB-IIIA NSCLC





- OS data were immature at this pre-planned DFS interim analysis
  - OS in the ITT population was not formally tested
  - A trend toward OS improvement with atezolizumab was seen in the PD-L1 TC ≥1% stage II-IIIA population

Case #2: Treatment Summary

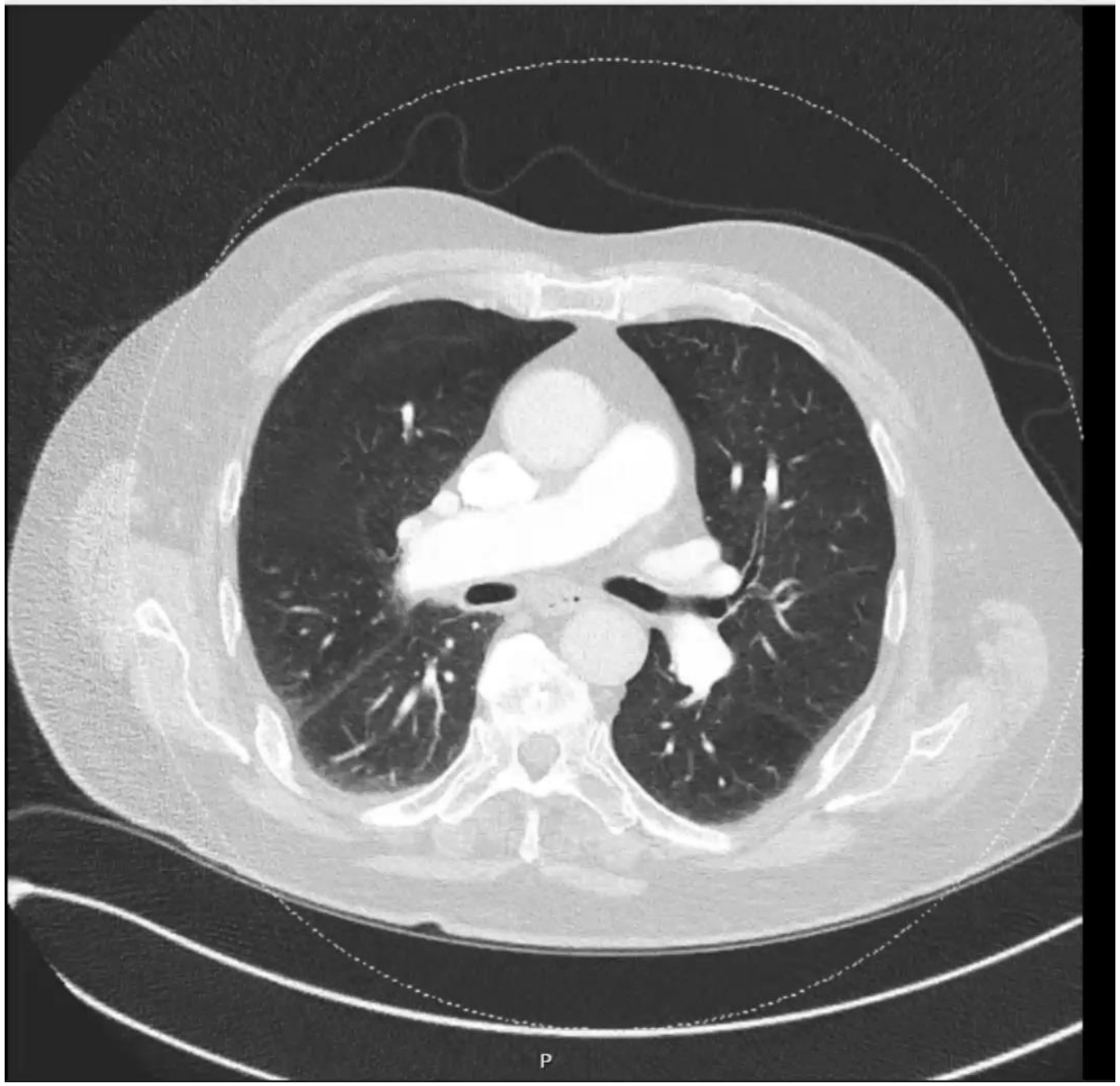
- Patient then underwent **robotic assisted middle lobe lobectomy**, **right upper lung** and **right lower lung wedge resections**, and **mediastinal lymph node dissection**.
- Pathology demonstrated **squamous cell carcinoma** with no involved margins or metastatic lymph nodes. Stage IIA, pT2bN0M0.
- Biomarkers: **TP53 R158P** and **PD-L1 TPS 10%**.
- Patient was started on **adjuvant atezolizumab** and is currently status-post **12 cycles**.

Case #3: Chemoradiation Therapy

Case #3: Presentation

- 76-year-old male, former-smoker with 30 pack-year history, presented to his primary care provider with complaint of **productive cough** with white phlegm.

- Workup eventually led to him undergoing a **CTA chest**, which showed a **band-like opacity** extending from the right hilum into the right lower lobe.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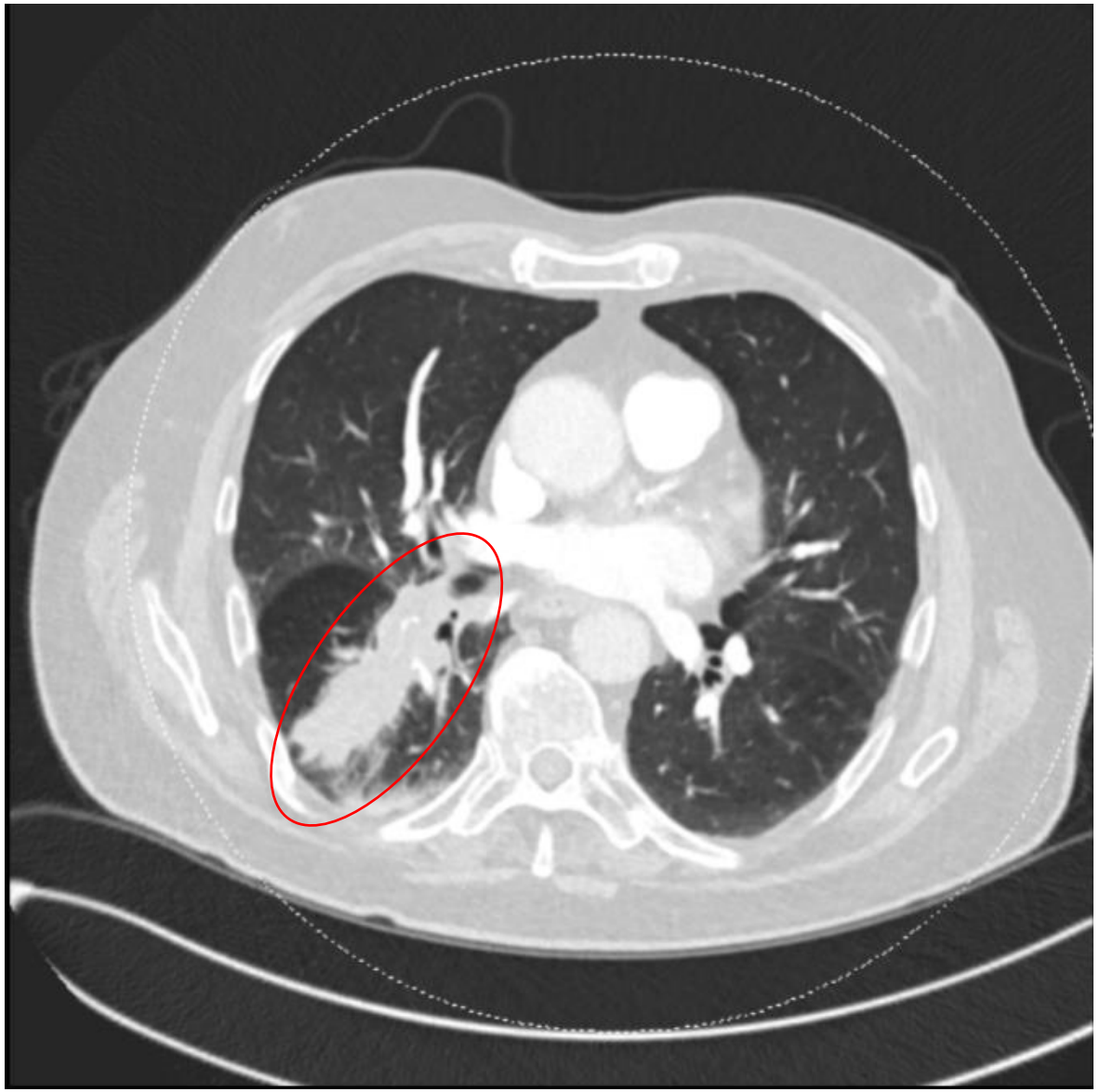
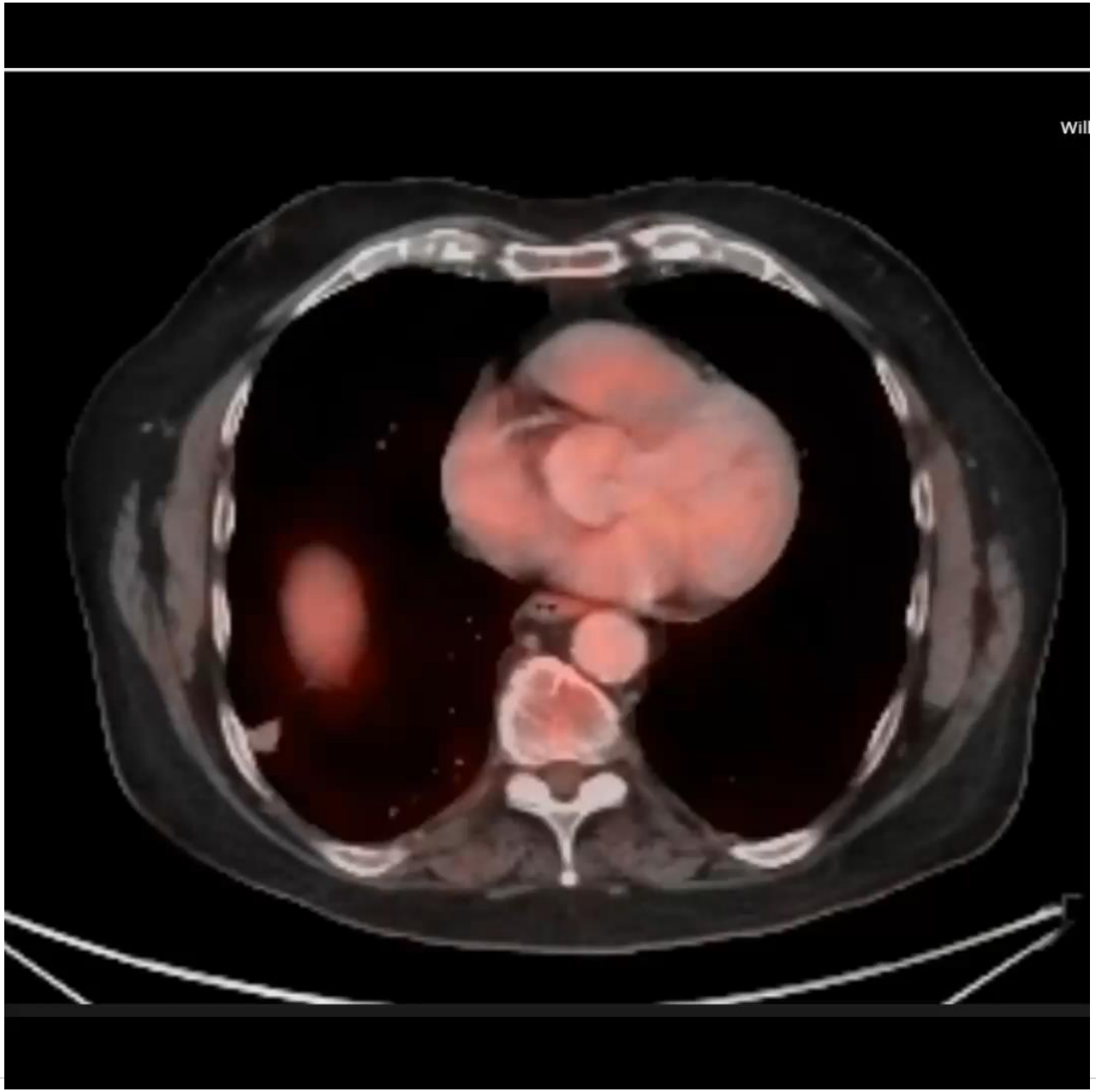
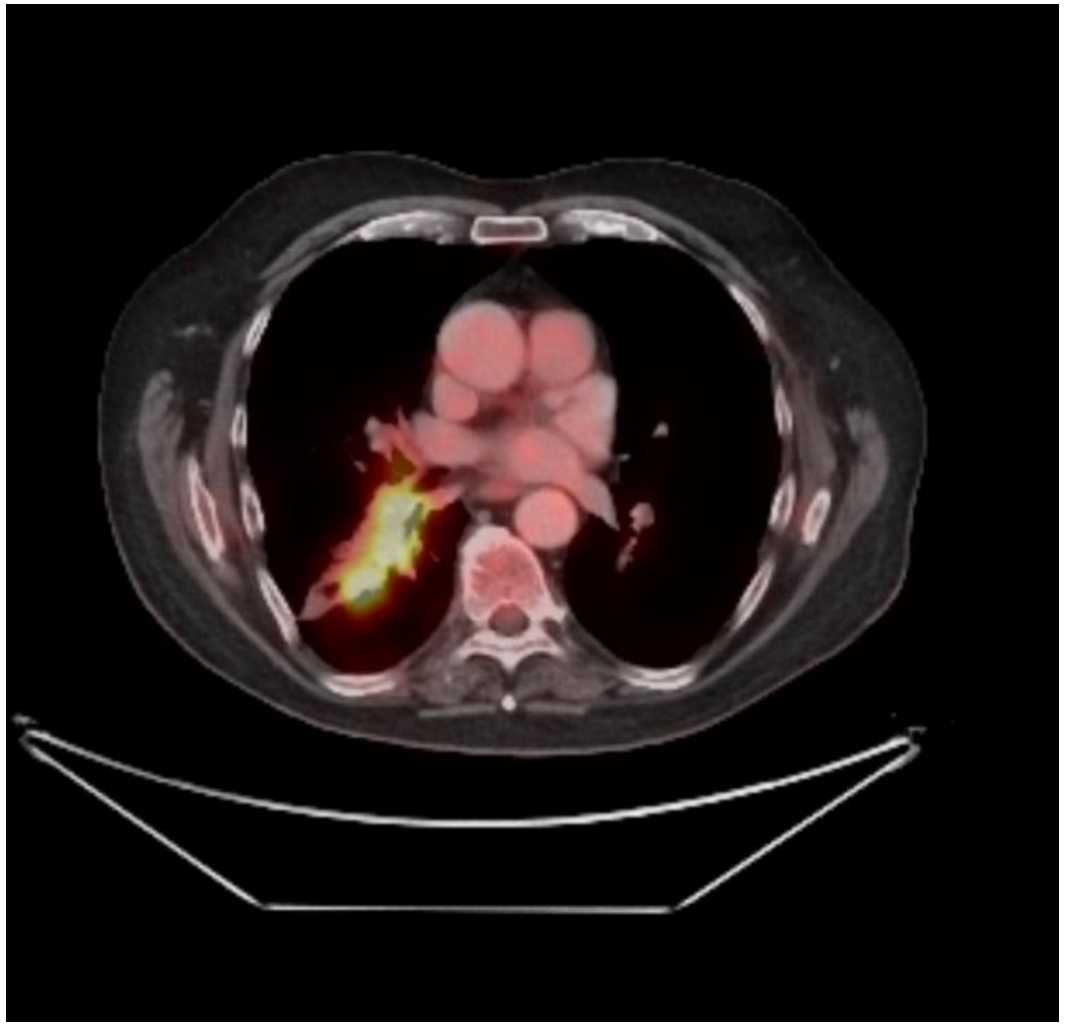


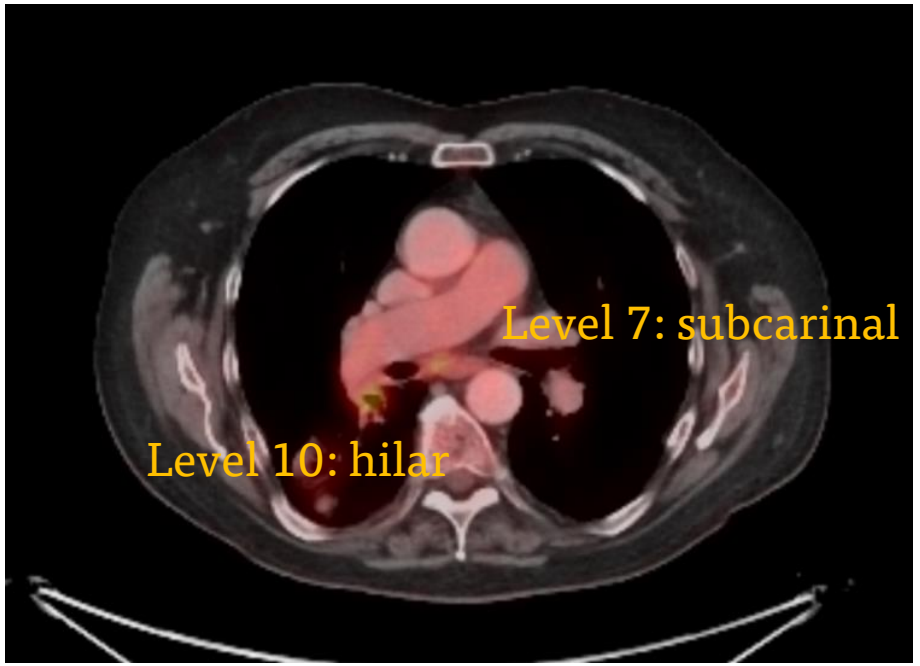
Case #3: Work-up

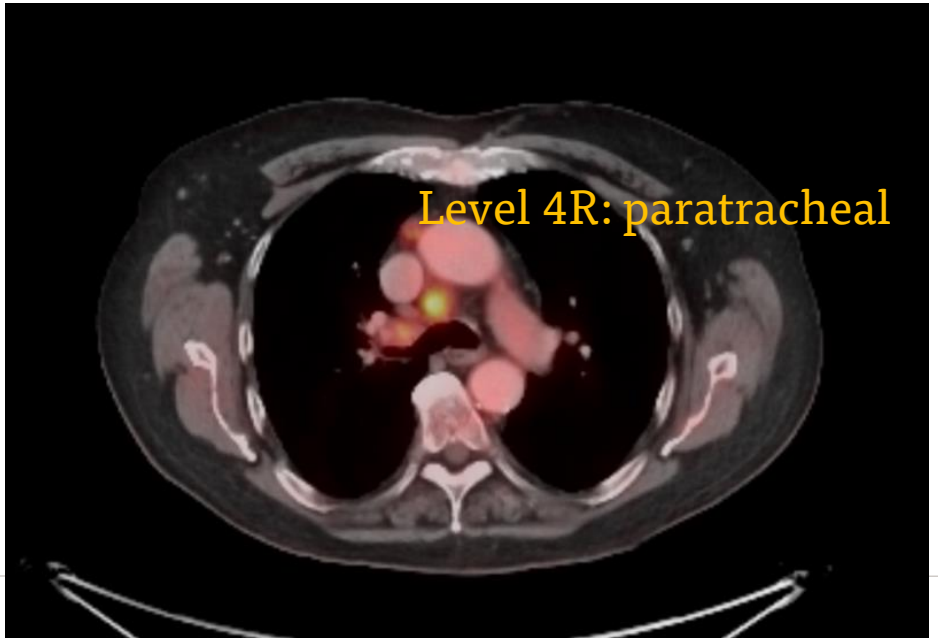
- He then underwent a PET/CT demonstrating an **intensely metabolic large right lower lobe mass** extending to the hilum. Moderately increased metabolic activity associated with **right hilar, subcarinal, and ipsilateral paratracheal** lymphadenopathy.

- MRI brain with no evidence of metastatic disease.






Level 7: subcarinal
Level 10: hilar


Level 4R: paratracheal

Case #3: Work-up

- Bronchoscopy and EBUS were performed. FNA biopsy of the right lower lobe mass showed **adenocarcinoma**, well-differentiated with mucinous features. Biopsy positive for adenocarcinoma from levels 4R, 7, and 10 lymph nodes.

- Staged **cT4N2M0**.

Genomic Alterations Detected	Allele Frequency	FDA-Approved Therapies in patient's tumor*	FDA-Approved Therapies in other tumor type*
KRAS (c.35G>T; **p.G12V**)	**10%**	**None**	**None**
STK11 (c.142A>T; **p.K48***)	**8%**	**None**	**None**
	TUMOR MUTATIONAL BURDEN STATUS (TMB)		
Intermediate			
	MICROSATELLITE STATUS (MSI)		
Stable			

Antibody (Clone) / Probe	Tumor Proportion Score (TPS)
PD-L1 (22C3) * FDA (Keytruda®) for NSCLC	TPS: 0%

Case #3: Presentation Summary

- 76-year-old male with 30 pack-years smoking history with newly diagnosed **stage IIIB (cT4N2M0) lung adenocarcinoma** of the right lower lobe, **KRAS-G12V** mutated, **PD-L1 TPS 0%.**

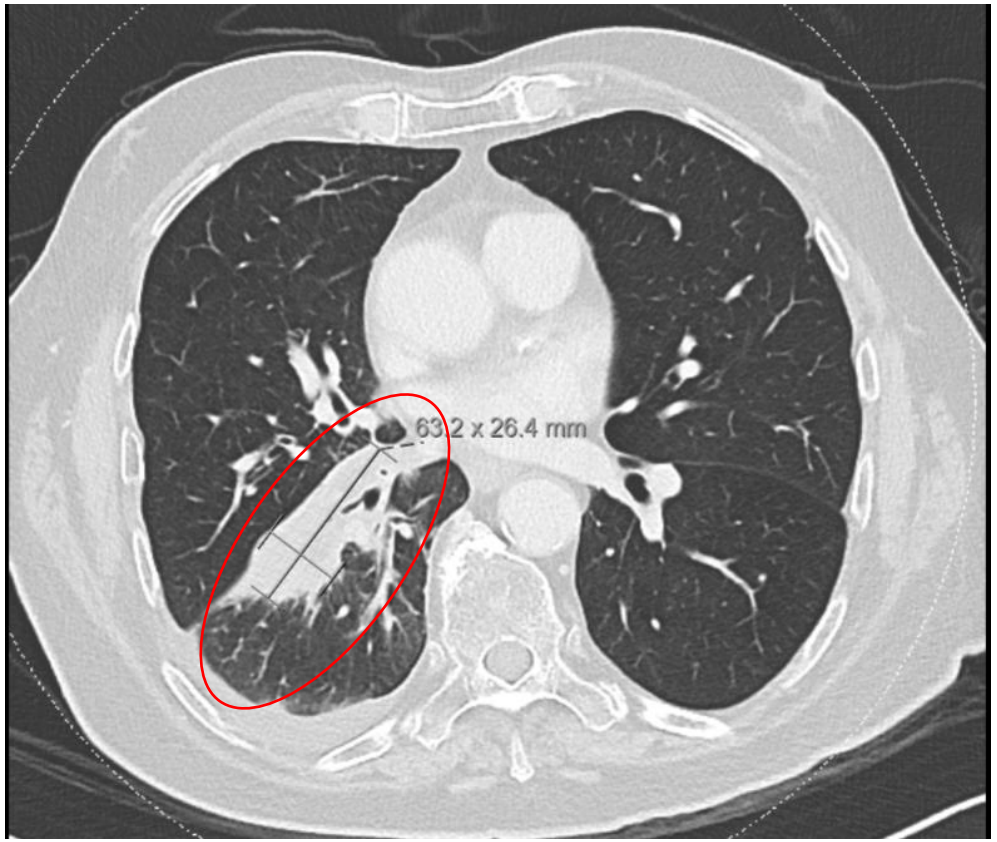
- Given the work-up thus far, what would you recommend for this patient?

Case #3: Treatment

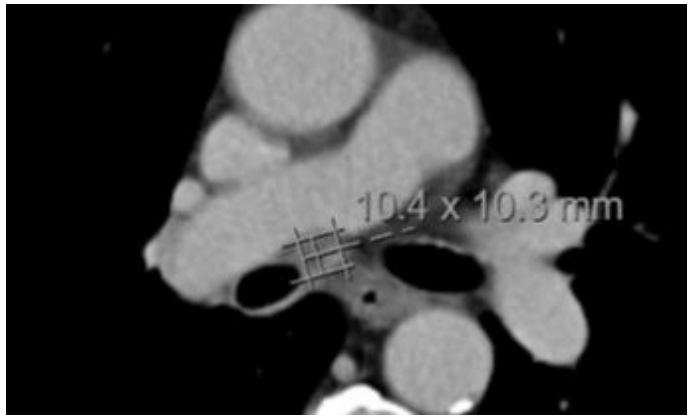
- Given multi-station N2 disease, patient was not a candidate for surgery.
- He was recommended definitive concurrent chemoradiation with weekly **carboplatin and paclitaxel** and radiation treatment to right lower lobe and mediastinum with IMRT (**60 Gy in 30 fractions**).
- Patient developed **pancytopenia** (WBC 1.3, ANC 1., platelet 143), and chemotherapy was held on the last week of chemoradiation.
- He also had grade 1 **esophagitis**, managed with Radiomix.
- After completion of chemoradiation, he was then initiated on consolidative **durvalumab**.

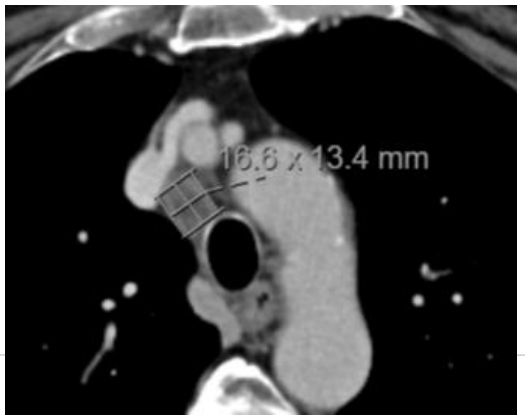
Case #3

- CT 1 month after CRT



Slight decrease 6.3 x 2.6 cm oval density right lower lobe.



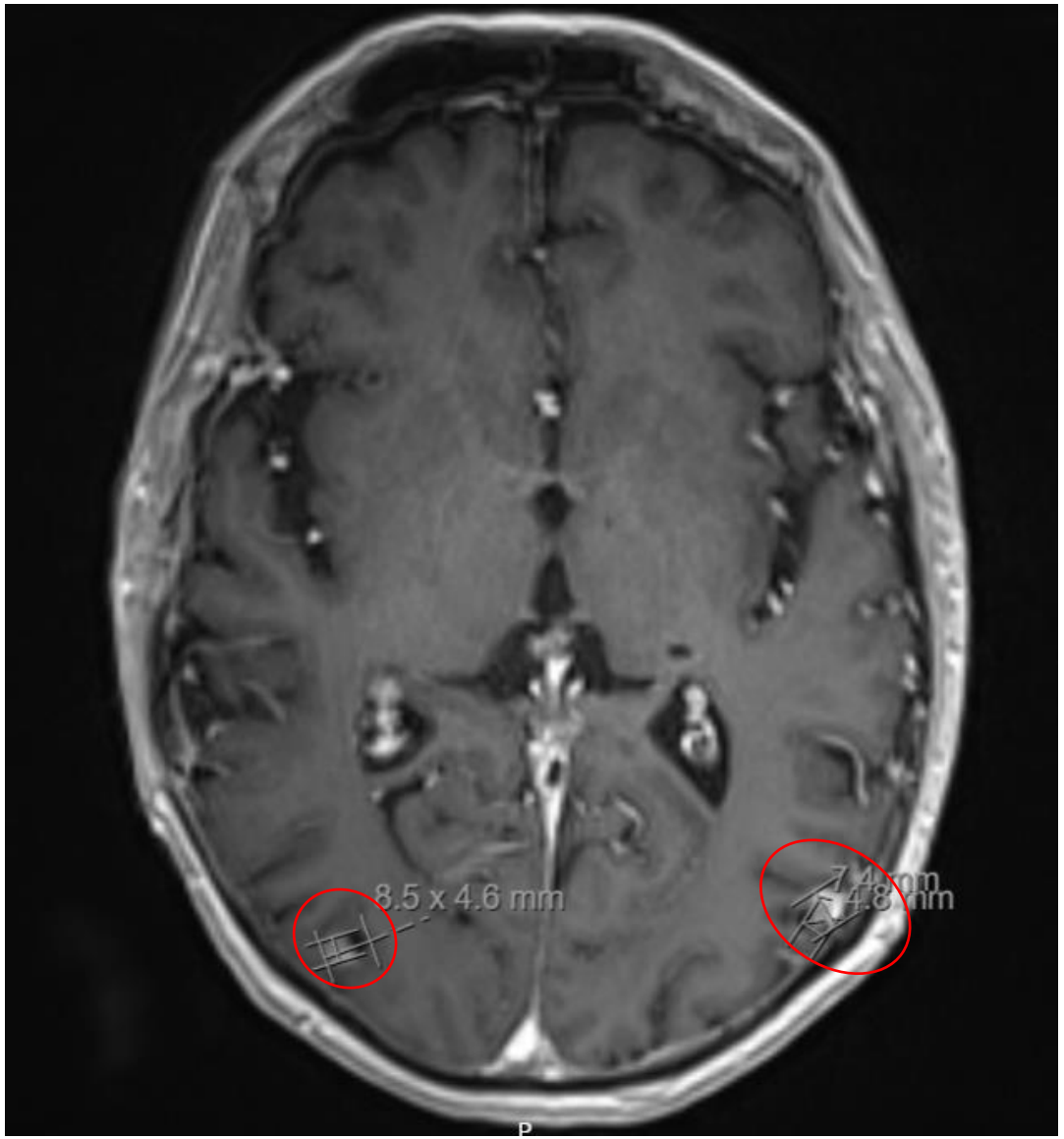


Similar in size **mediastinal** and **right hilar metastatic lymphadenopathy** with increased central low density/ necrosis.

Case #3

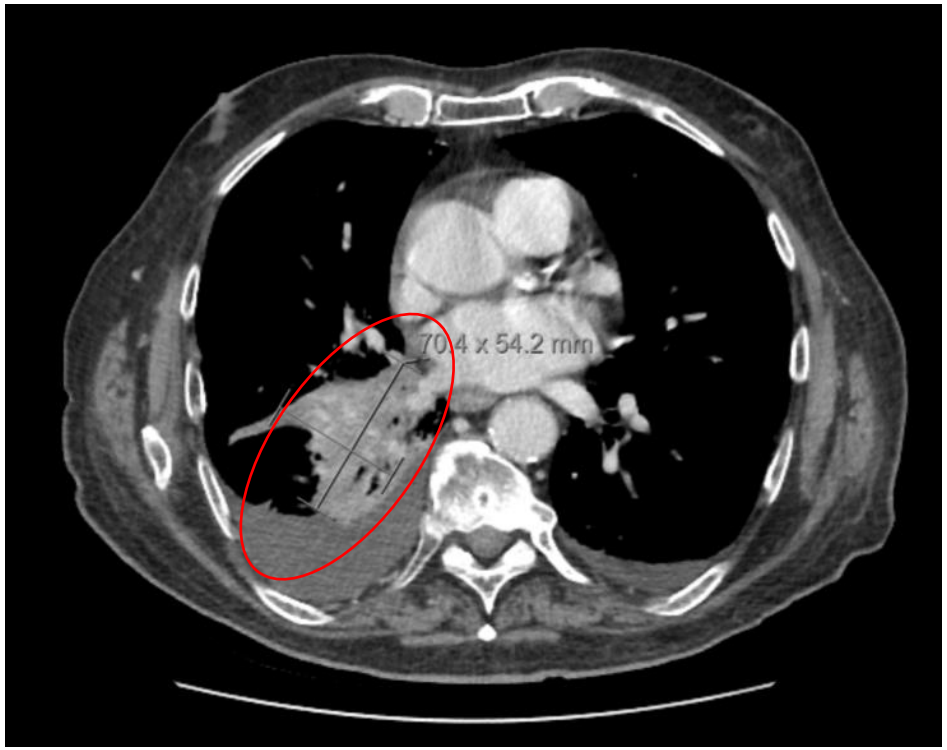
- 3 months after completion of CRT, patient developed severe headaches and back pain, 10 out of 10 in severity and presented to ETC.

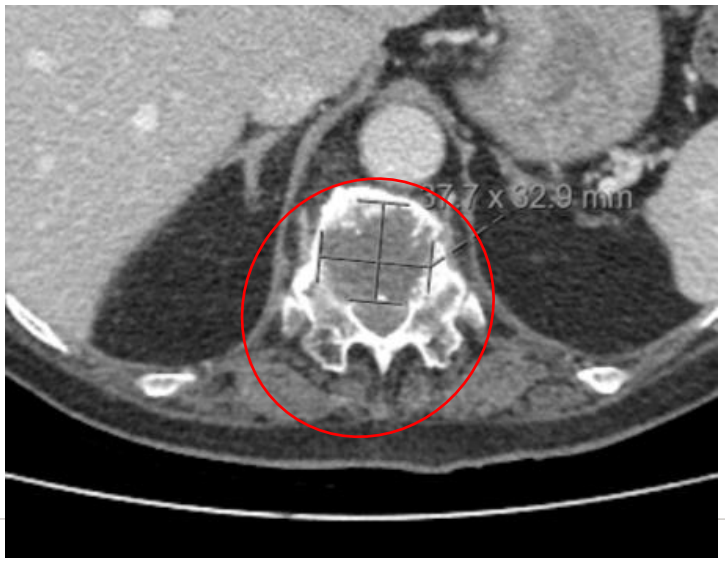
- He had an MRI brain that revealed new innumerable mostly **rim-enhancing lesions** in the cerebellum and supratentorial brain.

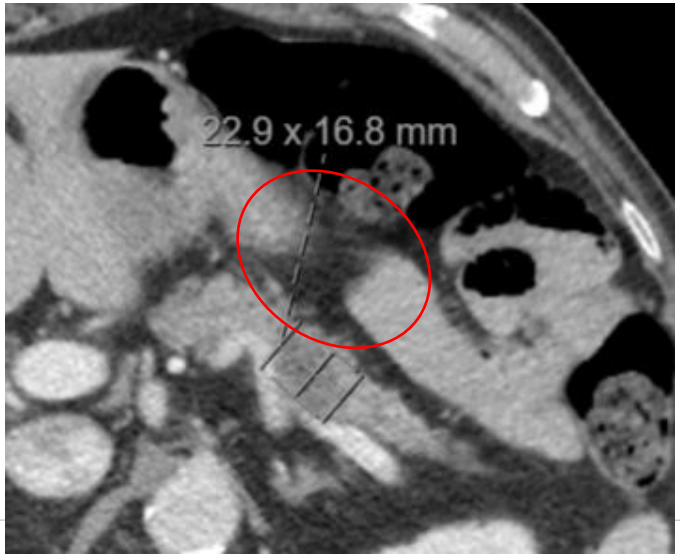


Case #3

- CT chest/pelvis showed:
  - An increase in size of the **right lower lobe consolidation**.
  - development of new **hilar** and **mediastinal** adenopathy
  - New right **supraclavicular** node
  - New metastases involving the right **axilla, left chest wall, liver, right adrenal gland, and pancreas**
  - New osseous metastases in left **scapula, left greater trochanter, right femoral head, and T12**.







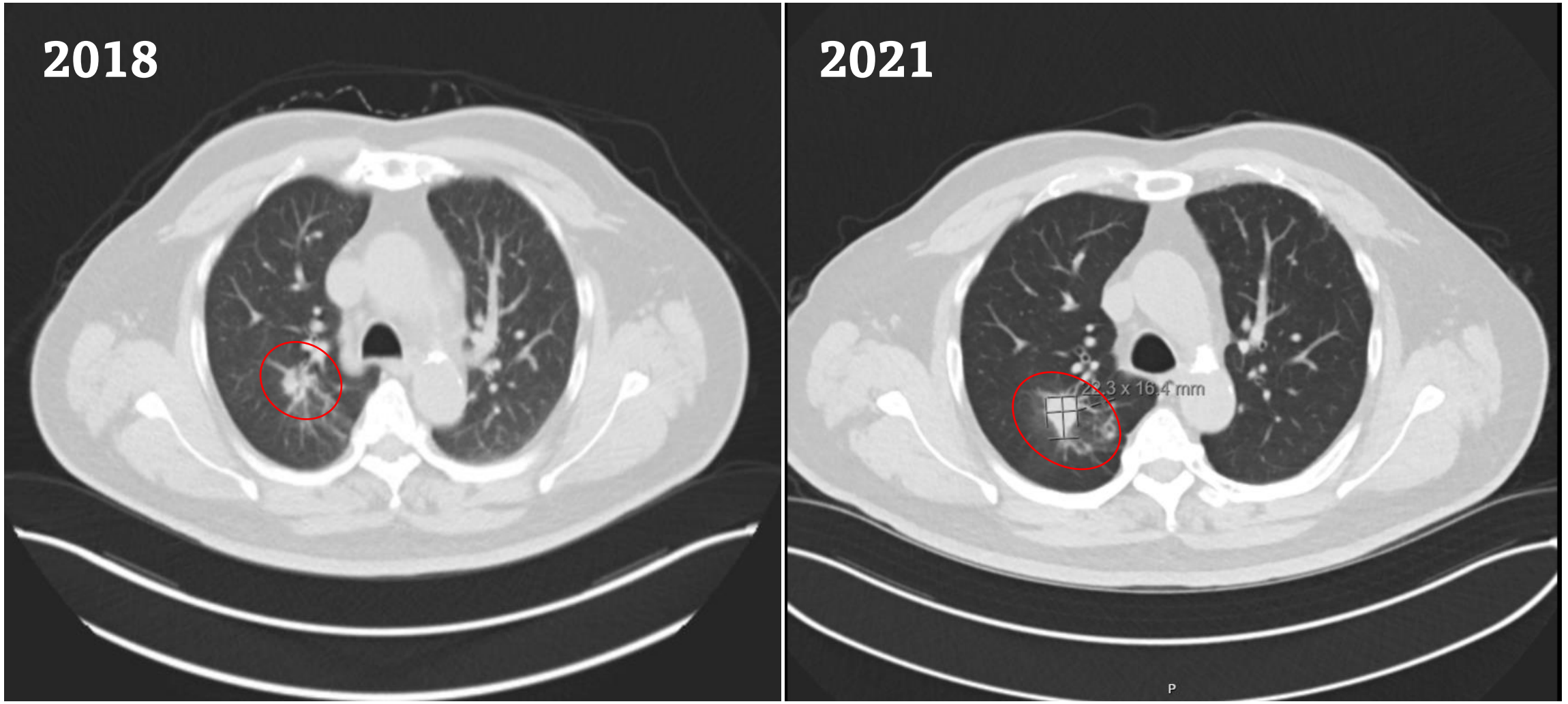
Case #3: Treatment Summary

- He received **whole brain radiation** with 30 Gy in 10 fractions and 20 Gy in 5 fractions to **T12-S3 and bilateral hip**.
- Patient completed radiation and was discharged home with hospice.

Case #4: Oligometastatic Disease

Case #4: Presentation

- 68-year-old male, former smoker with 50 pack-year history, was found to have a **right upper lobe nodule** (17 x 17 mm) on screening.
- PET was negative; patient was recommended to have annual imaging for monitoring but was lost to follow-up.
- CT chest several years later demonstrated mixed **heterogeneous right upper lobe nodule** (22 x 16 mm) with increasing ground-glass component.


2018
2021
22.3 x 16.4 mm
P

Case #4: Work-up

- Transbronchial biopsy of the nodule showed rare malignant cells consistent with **pulmonary adenocarcinoma**. FNA of 4R/7/3P lymph nodes were **negative** for malignant cells.
- PET showed a focus of **increased activity** in the right upper lung corresponding to the nodule on CT scan with increased ground-glass changes. **Two new satellite lesions**. A new focal destructive **bony lesion** in the left side of **C2**.
- Patient was not experiencing any neurologic symptoms at that time.

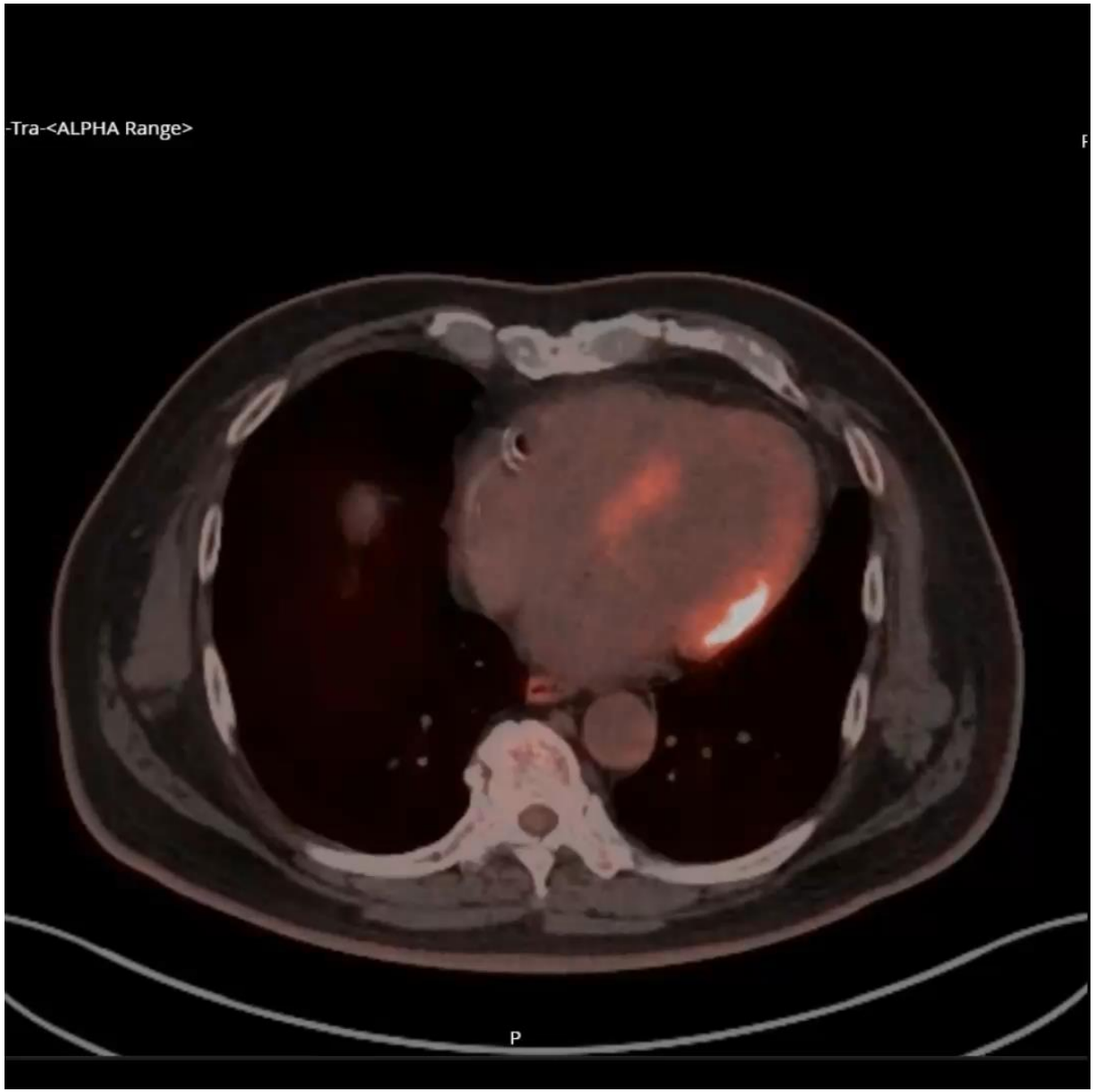
HopeSeq Lung

FORMALIN-FIXED PARAFFIN-EMBEDDED TISSUE (LUNG, RIGHT UPPER LOBE, FINE NEEDLE ASPIRATION X 5 PASSES AND TRANSBRONCHIAL BIOPSIES X 8, N21-00526-A2), COMPREHENSIVE GENOMIC ANALYSIS:

Genomic Sequencing Findings	Allele Frequency	FDA-Approved Therapies in patient's tumor*	FDA-Approved Therapies in other tumor type*
KRAS (c.34G>T, **p.G12C**)	**5%**	**Sotorasib**	**None**
TUMOR MUTATIONAL BURDEN STATUS (TMB)			
Low			
MICROSATELLITE STATUS (MSI)			
Stable			
PD-L1 22C3 FDA (KEYTRUDA) for NSCLC STATUS			
Expressed			
Tumor Proportion Score: 30%			
Intensity: 2+			
Testing for PD-L1 was performed at NeoGenomics. The complete reference laboratory report is attached as an image at the end of this report.			

*Treatment decisions are the responsibility of the physician. Drugs referenced in this report are for informational purposes based on current knowledge and are not intended to be comprehensive of all treatment options. Drugs listed may not necessarily be suitable for a given patient. Treatment decisions should be based on the independent medical judgment of the physician and should also consider all other clinical information on the patient.

No other alterations of potential clinical significance including *EGFR*, *ALK*, *BRAF*, *RET*, *ERBB2*, *ROS1*, and *MET* Exon 14 alterations were detected in the remaining targets of this assay.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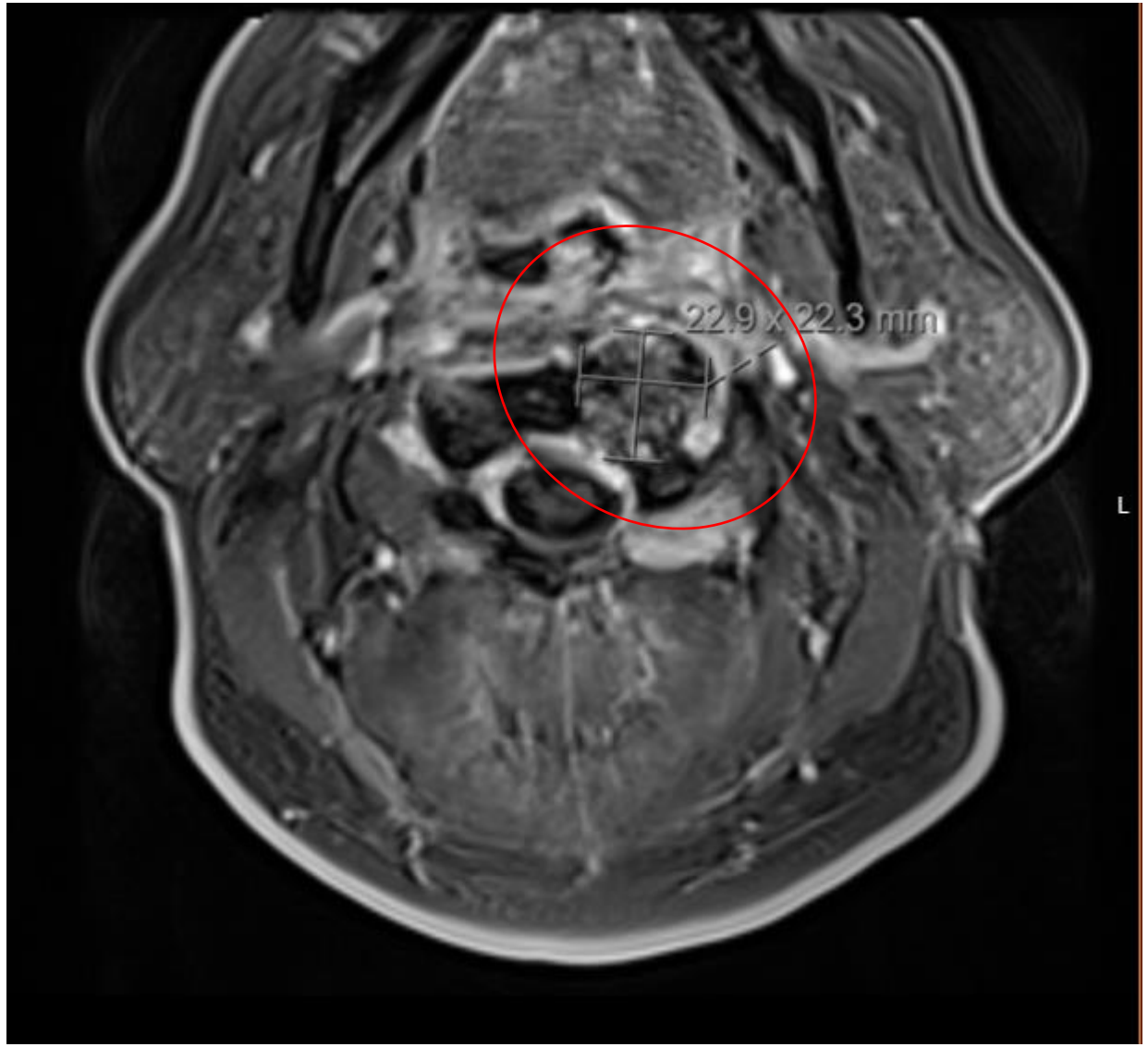
MRI Brain



Left C2 vertebral body lesion with heterogeneous contrast enhancement.

MRI brain with no evidence of brain metastases.

Case #4: Work-up

- Transbronchial biopsy of the nodule showed rare malignant cells consistent with **pulmonary adenocarcinoma**. FNA of stations 4R/7/3P lymph nodes were **negative** for malignant cells.

- PET showed a focus of **increased activity** in the right upper lung corresponding to the nodule on CT scan with increased ground-glass changes. **Two new satellite lesions**. A new focal destructive **bony lesion**.

- Patient was referred to Neurosurgery for possible biopsy of the C2 lesion. However, biopsy was not recommended given the location of the lesion.

- Case was discussed during Tumor Board. It was felt that the C2 lesion was most consistent with metastasis.

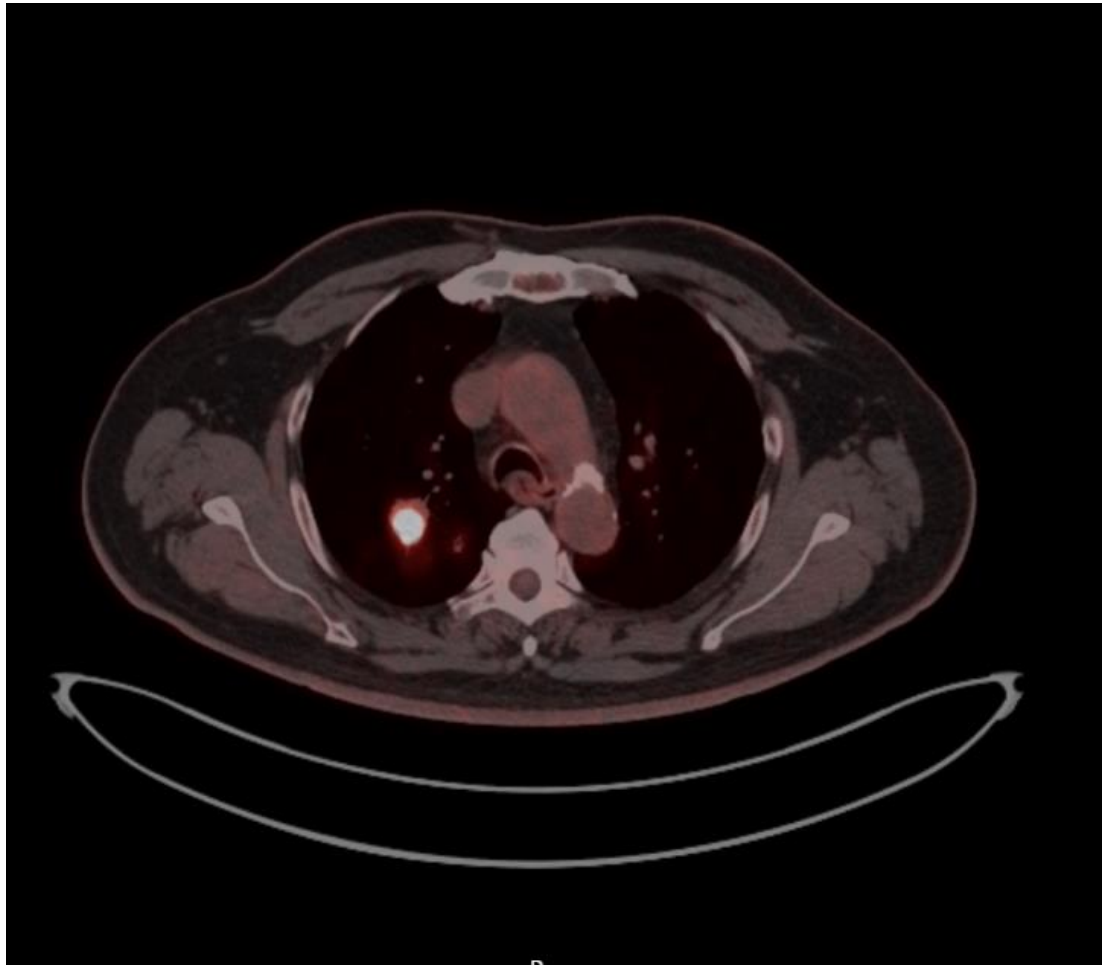
Case #4: Presentation Summary

- 68-year-old male with 50 pack-year smoking history with newly diagnosed oligometastatic NSCLC.
- Given the work-up thus far, what would you recommend for this patient?

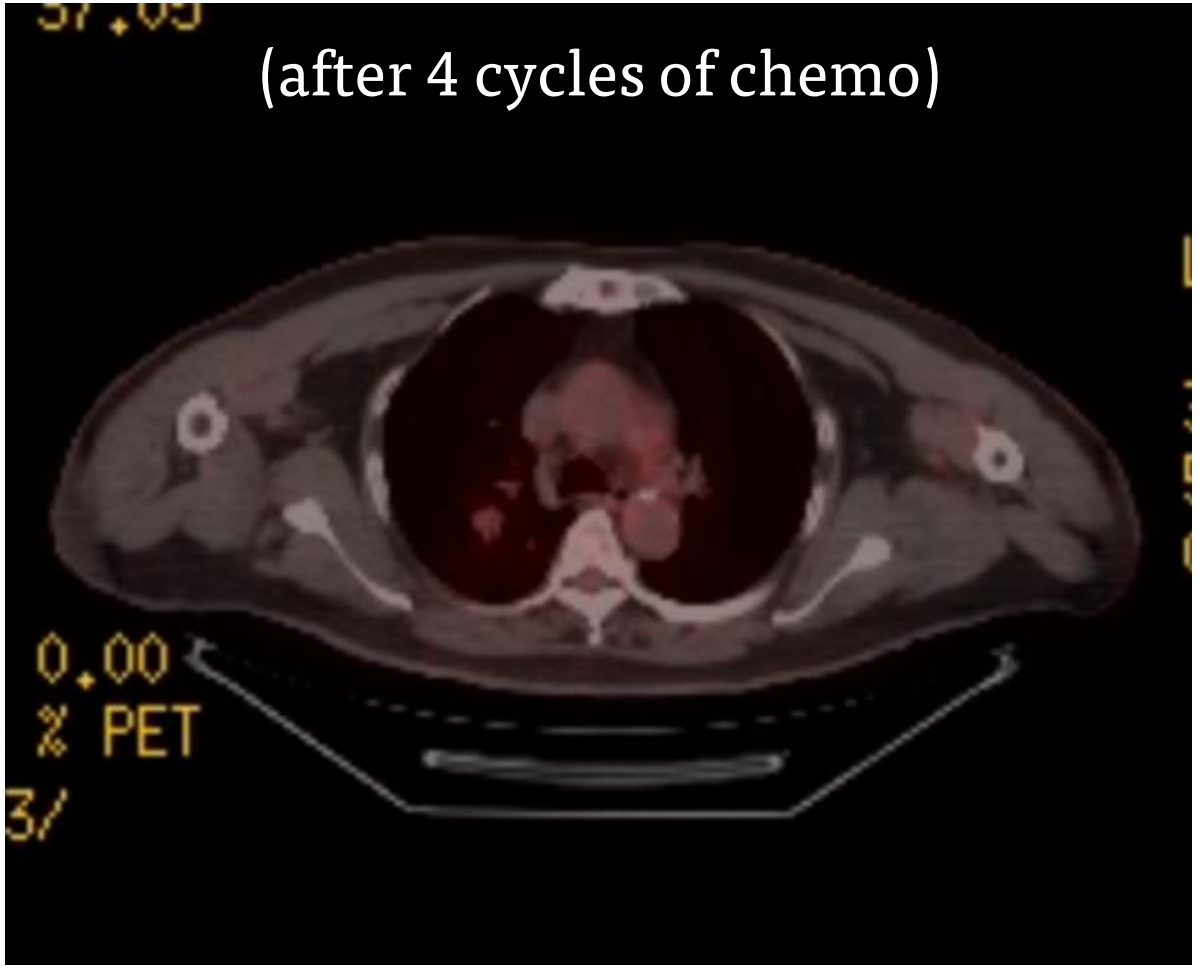
Case #4: Treatment

- Patient initiated systemic therapy with **carboplatin, pemetrexed, and pembrolizumab.**
- Patient was referred to Radiation Oncology for radiation to CT lesion to prevent the development of neurologic symptoms. He underwent **SBRT to C2 lesion** with 21 Gy in 3 fractions.
- **Carboplatin** was **discontinued** after 3 cycles due to elevated creatinine. He continued cycle #4 with pemetrexed and pembrolizumab.

Pre-treatment PET



Restaging PET



The spiculated right upper lobe nodule measures slightly smaller but is no longer FDG avid. No FDG avid lymphadenopathy or extra-thoracic sites.

Case #4: Treatment Summary

- Patient continued with **maintenance pemetrexed** and **pembrolizumab**.
- Given good treatment response, patient was referred to Radiation Oncology after cycle #7 of systemic therapy for **consolidative radiation**.
- He underwent SBRT to the right upper lung with 50 Gy in 5 fractions.
- Patient tolerated radiation treatment well with no notable side effects.
- Plan for patient to continue with maintenance therapy.