NATIONAL LUNG CANCER ROUNDTABLE

Ochsner | LSU Health SHREVEPORT

American Cancer Society® | Project ECHO®

Addressing Lung Cancer Biomarker Testing Through Project ECHO in Louisiana: Session 5

March 10, 2023

This project is generously supported by Amgen Oncology

Welcome to Session 5 of the Addressing Lung Cancer Biomarker Testing Through Project ECHO in Louisiana

Each ECHO session will be recorded and will be posted to echo.cancer.org

You will be muted with your video turned off when you join the call.
Use the buttons in the *black* menu bar to unmute your line and to turn on your video.
If you do not wish to have your image recorded, please turn OFF the video option.

Today's materials will be made available on echo.cancer.org

Please type your NAME, ROLE, and FACILITY in the chat box

This ECHO session takes place on the Zoom platform.
To review Zoom's privacy policy, please visit zoom.us/privacy

Remember: Do NOT share any personal information about any patient

Questions about Zoom? Type them in the chat box @ Leigh Davis

American Cancer Society®

Project ECHO®

Agenda Preview & Introductions

Sarah Thayer, MD, PhD, FACS;
Director

Ochsner LSU Health
Feist-Weiller Cancer Center

Specialty: Surgical Oncology

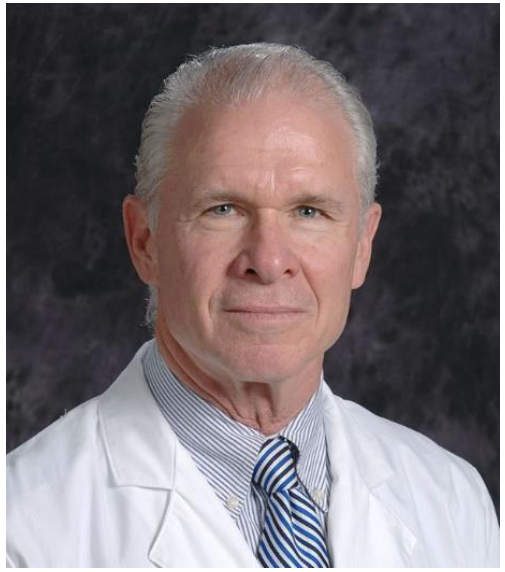
Today's Agenda

01	**Agenda Preview, Poll Results & Introductions** (10 minutes)
02	**Didactic Presentation: *Navigating Insurance Complexities*** (20 minutes)
03	**Didactic Q/A** (5 minutes)
04	**Case Presentation** (5 minutes)
05	**Case Presentation Recommendations & Discussion** (10 minutes)
06	**Post-Session Poll & Wrap Up** (5 minutes)

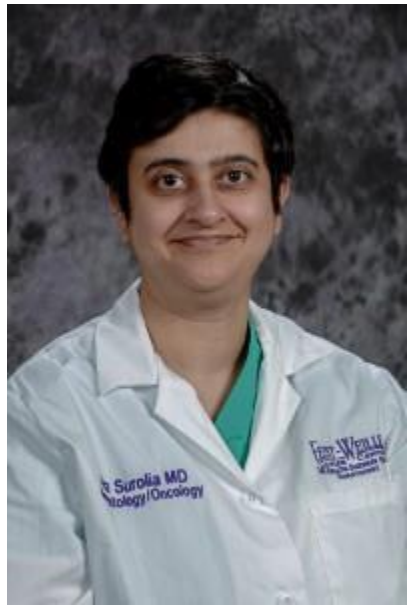
Meet our Louisiana Echo Hub Faculty Members

Robert Holladay, MD, FCCP
Professor of Clinical Internal Medicine; Program Director, Interventional Pulmonary Fellowship Program Medicine Pulmonary Critical

David Chambers, MD
Assistant Professor-of Clinical Internal Medicine, Associate Program Director of the Pulmonary and Critical Care Fellowship, Director of Lung Cancer Screening
Medical Pulmonary



Robert White, MD, FACS
Chairman and Professor of Surgery
John C. McDonald, MD Endowed Chair of Surgery

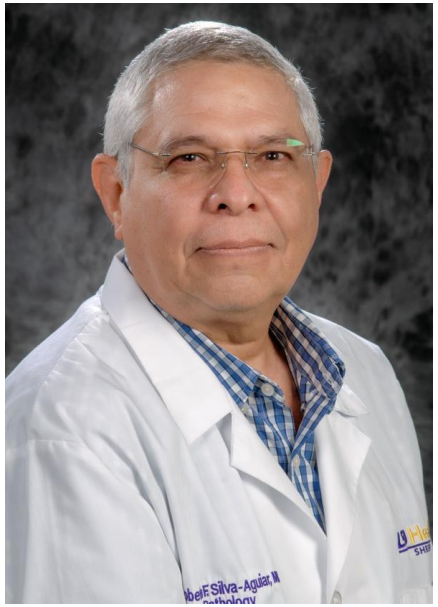


Ira Surolia, MD
Assistant Professor
Feist Weiller Cancer Center

Kavitha Beedupalli, MD
Associate Professor – Clinical Feist Weiller Cancer Center

Meet our Louisiana Echo Hub Faculty Members

Brian G. Fuller, MD
Associate Professor
Radiation Oncology
Feist Weiller Cancer Center



Roberto Silva, MD
Associate Professor of Pathology and Translational Pathobiology
Pathology Department

Troy Richards, MD
Clinical Assistant Professor of Radiology Radiation Oncology Department

Carlos Previgliano, MD
Professor of Radiology, Clinical Specialist Thoracic / Cardiothoracic Radiology

<u>Project Staff</u>
Lisa LaChance, MBA- Project Manager
Rachel Langford RN, OCN
Darren Guin, IT Analyst IV

Introductions: Meet our Louisiana Spoke Sites

Ochsner | LSU Health Shreveport

North Caddo Medical Center

Natchitoches Regional Medical Center

DeSoto Regional Health System

Lourdes Physician Group

Reminder: Please type your ***name, role, and facility*** in the chat box

Marc Matrana, MD

Director, Precision Medicine
Endowed Professor of Experimental Therapeutics
Associate Director of Clinical Cancer Research, Ochsner Health

Kevan Simms

Assistant Vice President of Precision Medicine at Ochsner Health

Didactic Presentation:
Navigating Insurance Complexities

Ochsner Precision Medicine

ACS – Somatic Testing

3/10

Agenda

- These slides are considered confidential and not for distribution
- Ochsner & Precision Medicine Overview – Dr. Marc Matrana, Sr. Physician and Medical Director of Precision Medicine Program
- Ochsner Somatic Testing Overview – Kevan Simms, AVP – Precision Medicine

Biomarkers, Cancer & the Law

Marc R. Matrana, MD, MS, FACP
System Medical Director of Precision Medicine
Endowed Professor of Experimental Therapeutics
Ochsner Health

What is Precision Medicine?

- Undercovers the underlying molecular alterations that drive health and disease
- Uses biomarkers to tailor health care on an individual patient level
- Most rapidly involving field in medicine, having a bigger impact each week.

No field in medicine will be untouched by this revolution.

What is Precision Medicine?

Risk Assessment

- Hereditary screening for risk stratification
- Population based screening

Diagnosis

- Multi-cancer early detection (MCED)
- Rapid whole genome sequencing (WGS) in neonates and others
- Early detect of disease

Treatment

- Pharmacogenomics (PGx)
- Next-generation sequencing (NGS)
- Single gene-drug pairs

Getting the best medicine to each individual patient at the right time and the right dose based on advanced molecular and genomic technologies.

Next Generation Tumor Sequencing

Very important tool for cancer treatment

Allows for testing hundreds of gene mutations from a single tissue or blood sample.

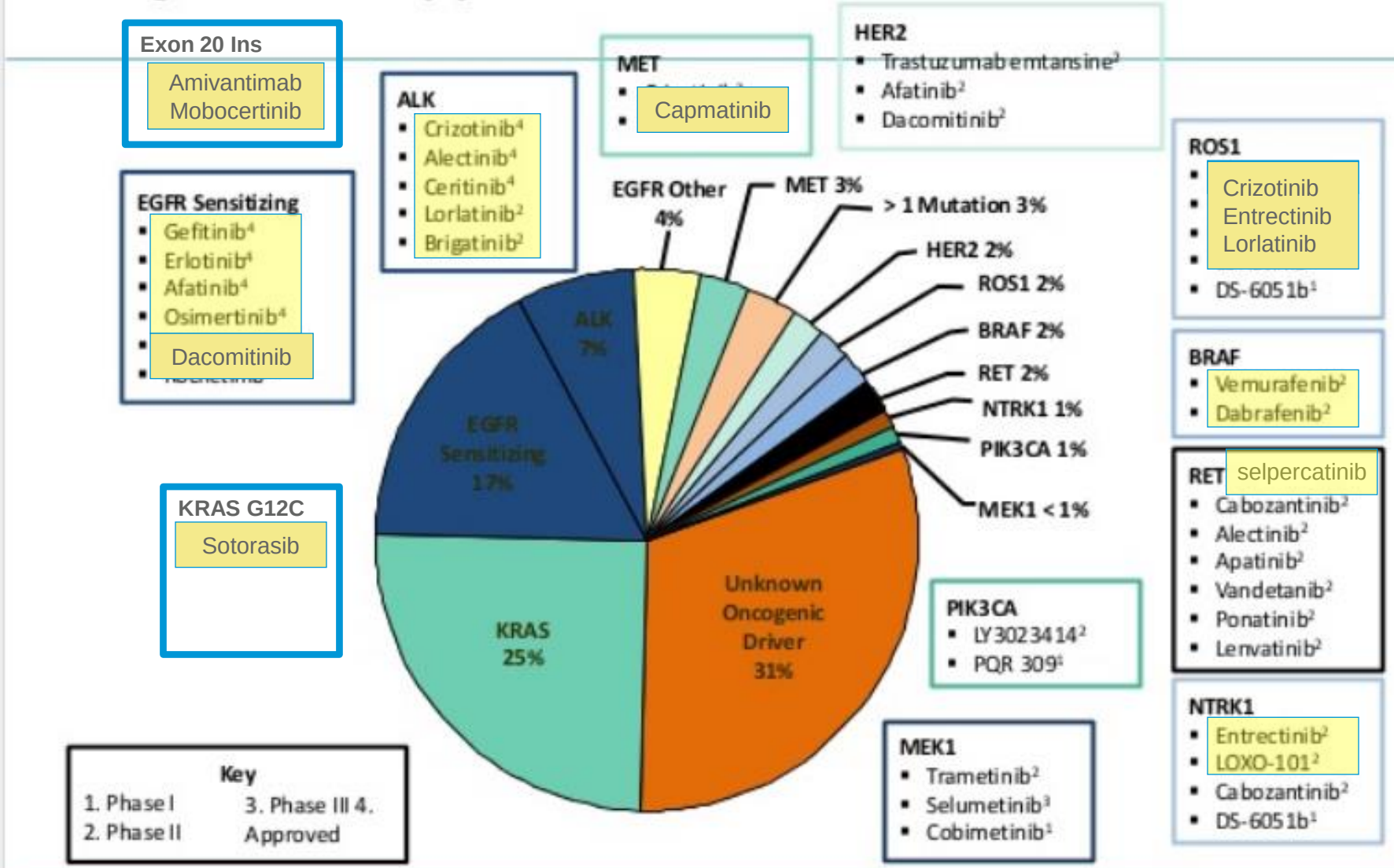
Provides the most personalized therapy options available.

Finds actionable mutations >40% of the time

Costs are dropping drastically

Allow for stratification to clinical trials

Targeted Therapy for Adenocarcinoma

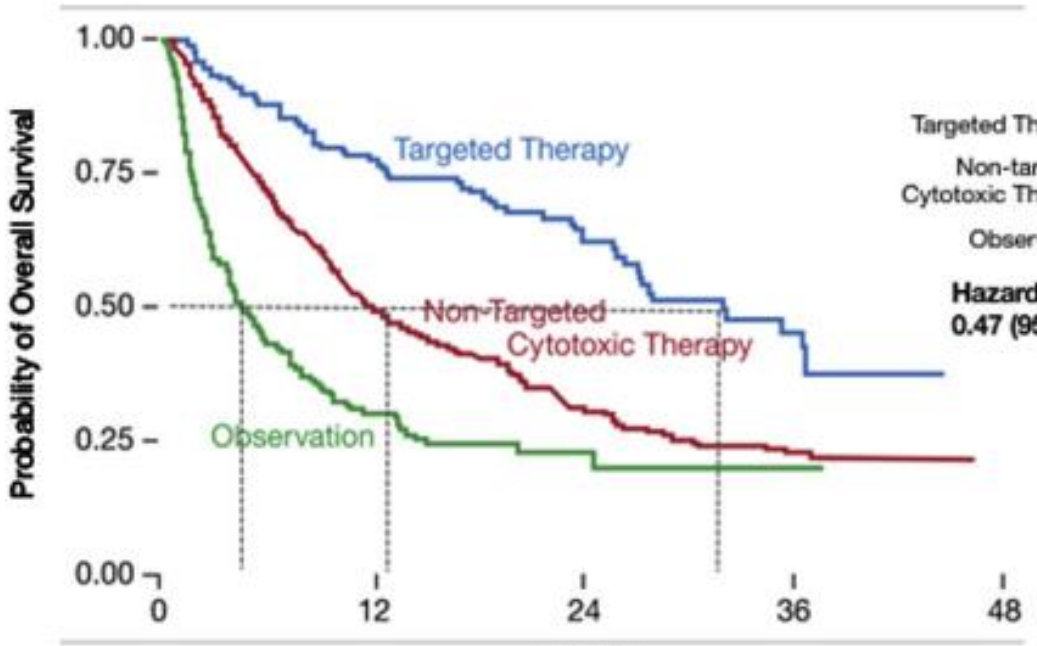


Tsao AS, et al. J Thorac Oncol. 2016;11:613-638.

Outcomes in NSCLC in Patients with Actionable Driving Mutations

Median OS 31.8 months

Median OS 12.7 months



	No. of Patients	Events	Median OS Mo (95% CI)
Targeted Therapy	131	58	31.8 (26.8-NA)
Non-targeted Cytotoxic Therapy	482	309	12.7 (11.0-15.5)
Observation	192	118	5.1 (3.9-7.3)

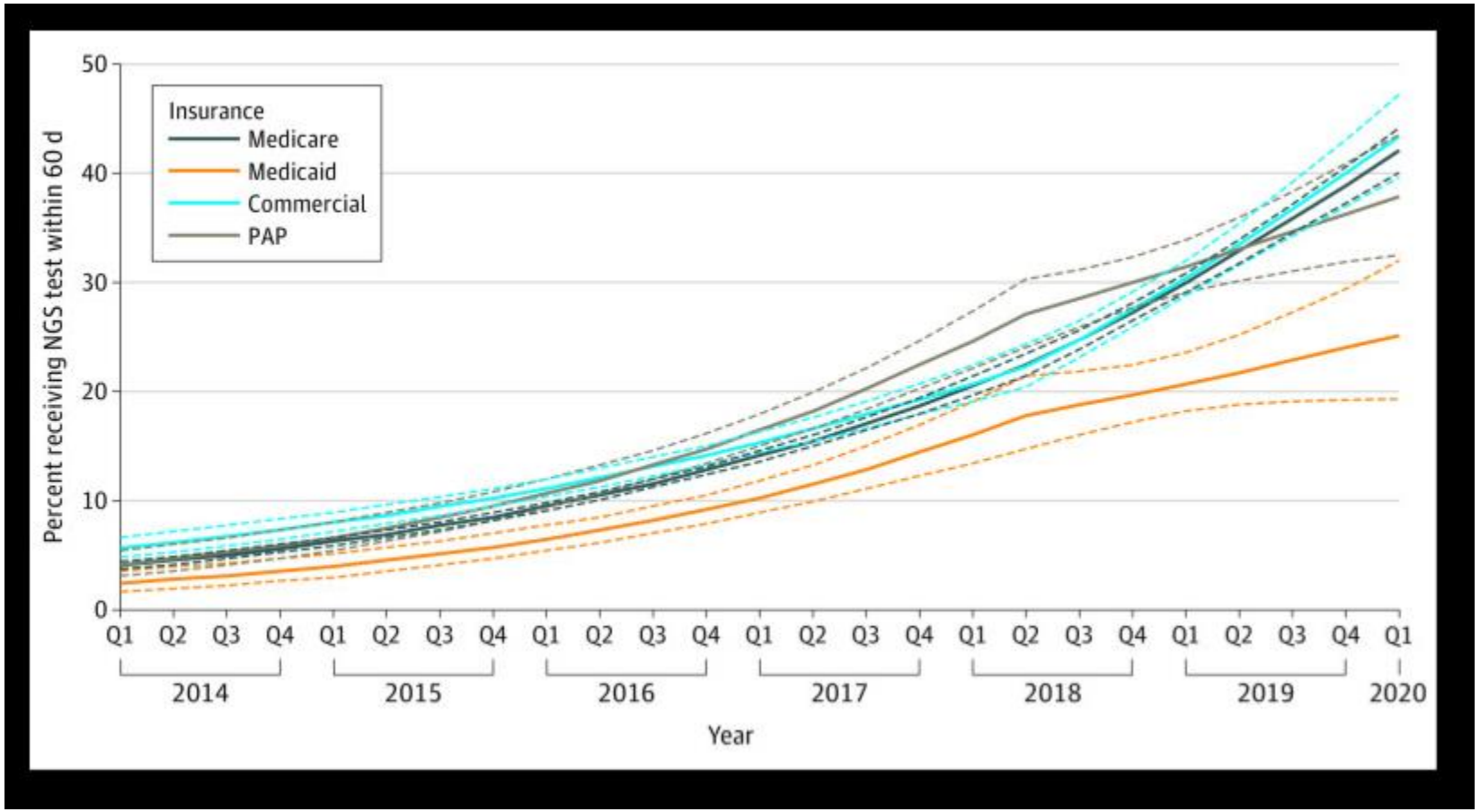
Hazard ratio for death (Targeted vs Non-targeted): 0.47 (95% CI, 0.36 to 0.63), Log rank p < 0.0001

No. at Risk					
Targeted Therapy	131	98	56	19	0
Non-targeted Cytotoxic Therapy	482	236	82	37	0
Observation	192	47	9	1	0

19.1 month difference in OS between TT vs non-TT in NSCLC

Gutierrez ME, Choi K, Lanman RB, Licitra EJ, Skrzypczak SM, Pe Benito R, Wu T, Arunajadai S, Kaur S, Harper H, Pecora AL, Schultz EV, Goldberg SL. Genomic Profiling of Advanced Non-Small Cell Lung Cancer in Community Settings: Gaps and Opportunities. Clin Lung Cancer. 2017 Nov;18(6):651-659. doi: 10.1016/j.cllc.2017.04.004. Epub 2017 Apr 13. PMID: 28479369.

Patients receiving NGS within 60 days of diagnosis



CAGLA

Cancer Advocacy Group of Louisiana

CANCER ADVOCACY GROUP OF LOUISIANA

Legislative Advocacy

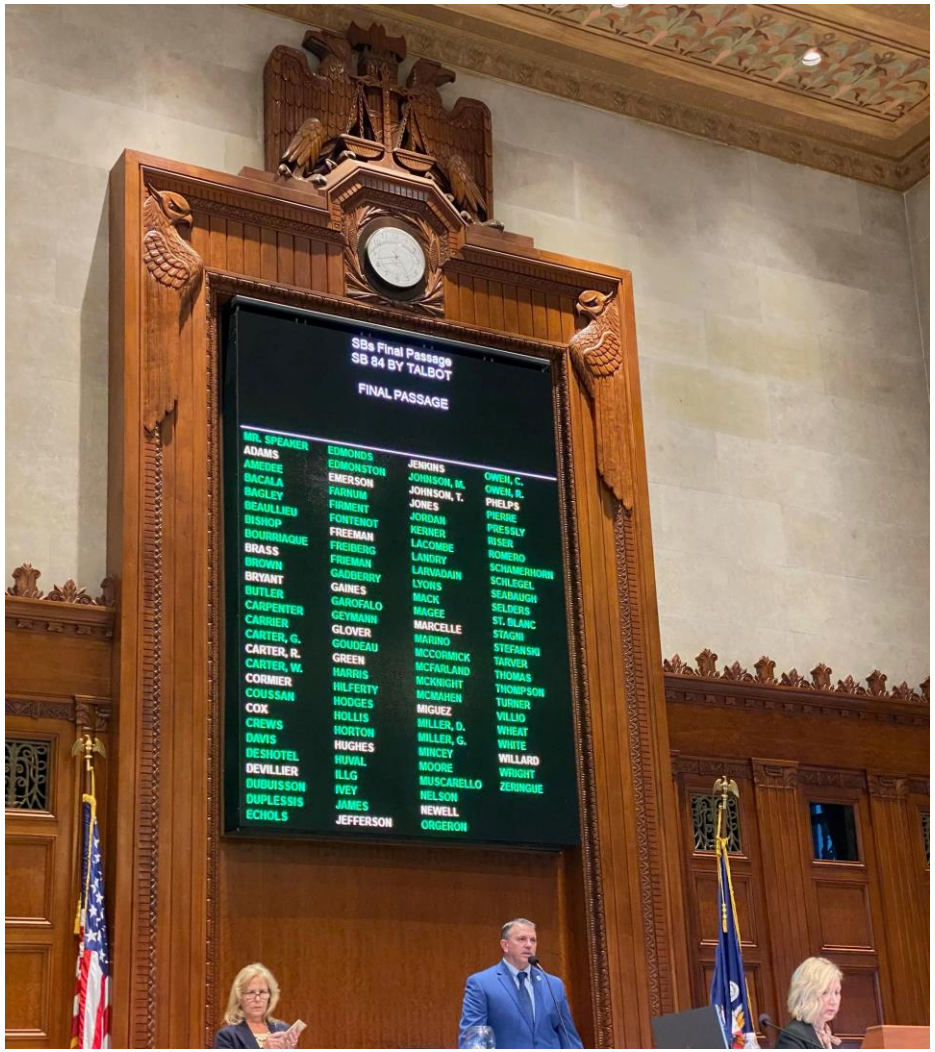
- SB 204 (2020) conceived and written by Dr. Matrana
  - Unanimously passed House and Senate, Signed into law
  - Mandated insurance coverage of precision medicine treatments for cancer patients

- Also in 2020, we amended LA revised statue 22:1044 mandating insurance coverage of phase 1 clinical trial patients with cancer

CAGLA
Cancer Advocacy Group of Louisiana

Legislative Advocacy

- SB 84 (2021) and SB 118 (2022) conceived and written by Dr. Matrana - now signed into law
  - Mandates insurance coverage of genetic/genomic testing in cancer patients
- SB 146 (2022) – Amendment which strengthens SB 204 (2020)
- These bills are progressive and unprecedented and serve as examples for other state legislatures and national efforts



CAGLA
Cancer Advocacy Group of Louisiana

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Somatic Testing at Ochsner

Ochsner Health

Somatic Testing Overview

- In August of 2022, Ochsner established electronic orders/results integration with Tempus for Somatic testing. This utilized the Epic Genomics Module.

- Selection process of a partner lab:
  - Informal ROI
  - Heavy participation from Clinicians
  - Tissue & Liquid required
  - Established ability to HL7 required
  - Lab Service Agreement in place
  - No BAA/Covered Entity

Criteria	
NGS Tissue	
NGS Tissue TAT	
NGS QNS Tissue	
NGS QNS Lung	HRD
NGS Liquid	Knowledge base/interpretation expertise
NGS Liquid TAT	Customer base
NGS QNS Liquid	On-site coordinator
PDL1	Cost/Billing
PDL1 TAT	Clinical Trials Matching
PDL1 clones	HL7 Integration

Somatic Testing Overview

- Project timeline ~4-6 months
- Primary PM provided by Tempus
- Data Governance was a critical path for approval/initiation given the sensitivity of “Genetic Results”
- Ochsner resources:
  - PM
  - Data Integration – HL7
  - Genomics Analyst
  - Beacon Analyst
  - Lab Analyst
  - Clinical Educator
  - HIM, Legal, Compliance, MyChart
  - Clinicians (for validation and design)
  - Process/Workflow expert desirable

Somatic Testing Overview

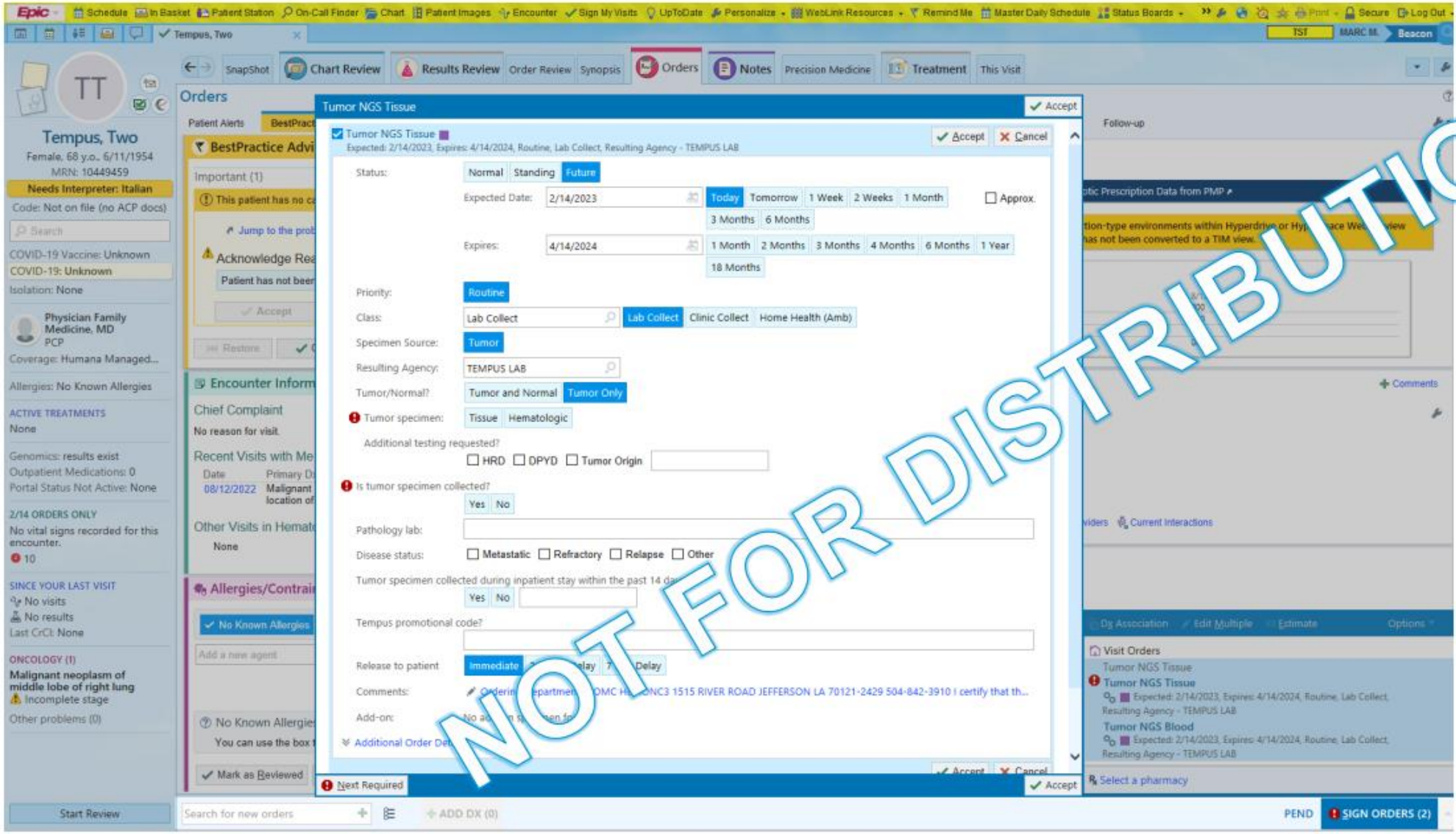
- Pathology initiated ordering was a priority
- This allows the process of ordering & specimen procurement to be expedited by 2 weeks or more
- Goal is to have results available to Oncology as part of their first visit with providers
- = Targeted therapy earlier = Improved patient outcomes

- This is NOT easy
- Oncology/Pathology collaborated to create an Algorithm for reflex ordering

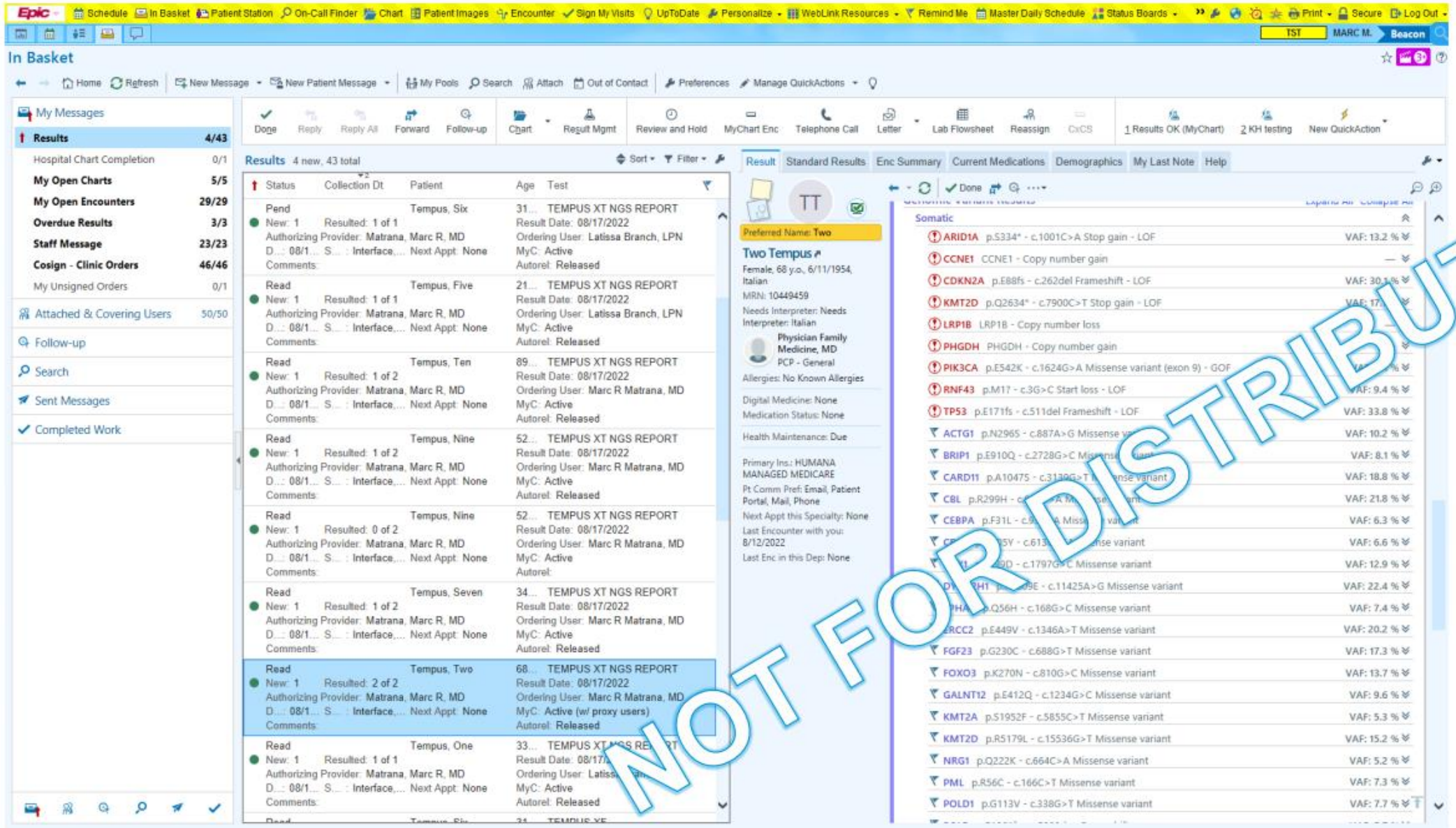
Organ System	PRIMARY REFLEX in SoftPath Dx (pathologist order at primary dx)	DISTANT MET REFLEX in SoftPathDx (pathologist order on targeted biopsies of mets, stage 4 diease)	SCANT SPECIMENS (consult to Yang, Chung, or Galliano for review)	ORDERABLE in EPIC for advanced disease (nurse navigator or oncologist)- Secretaries will contact you
Breast	1. ER, PR, HER-2, Ki-67 IHC (in-house) 2. H2BR: HER-2 FISH (if 2+ IHC)	1. ER, PR, HER-2, Ki-67 IHC (in-house) 2. H2BR: HER-2 FISH (if 2+ IHC) 3. TRIPLE NEGATIVE ONLY: Tempus xT NGS panel + 22C3/CPS (PD-L1), cut 5 unstained upfront (ribbon with no trim)		1. ER, PR, HER-2, Ki-67 IHC (in-house) 2. H2BR: HER-2 FISH (if 2+ IHC) 3. TRIPLE NEGATIVE ONLY: 22C3/CPS (PD-L1), cut 5 unstained upfront (ribbon with no trim)

- Tight collaboration and alignment between Pathology, Clinical Lab, Oncology, Tempus. Workflow can be complicated and require multiple rounds of review and adjustment.
- “Outsourced Pathology” has been a barrier we have not overcome to this point. Oncologists initiate in these settings.

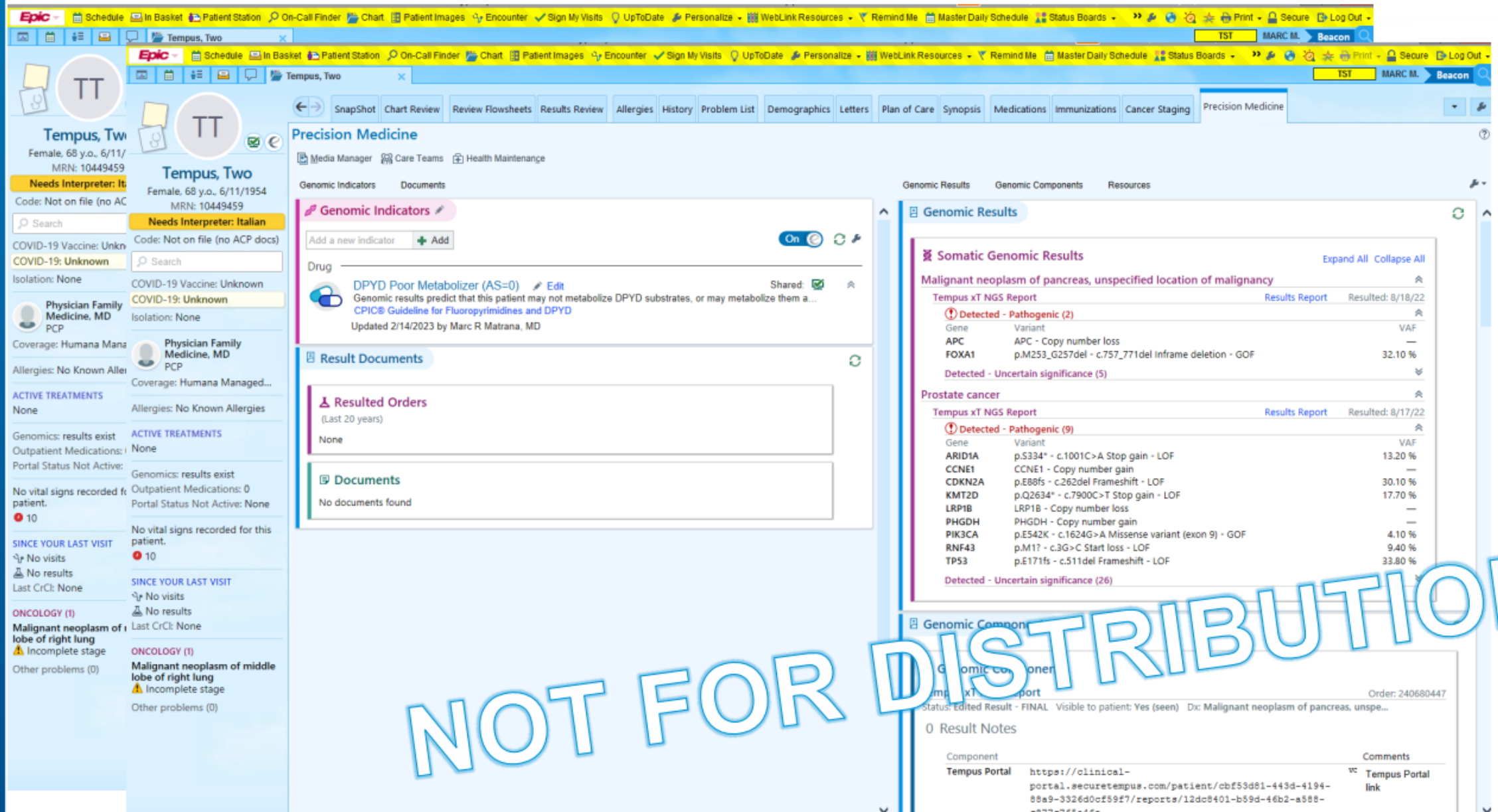
What is looks like - Order Entry



What it looks like - InBasket



What it looks like – Chart Review



What is looks
Tempus PDF

Date of Birth
02/03/1952

Sex
Male

Physician
[redacted]

TEMPUS | xT
648 gene panel

Tumor specimen:
Lung
[redacted]
Tumor Percentage: 40%
(post microdissection)

Normal specimen:
Blood
Collected 7/27/2022
Received 7/29/2022

GENOM

Somatic - Potentially Actionable — Variant Allele Fraction

PIK3CA	p.E542K Missense variant (exon 9) - GOF	4.1%

Somatic - Biologically Relevant

TP53	p.E171fs Frameshift - LOF	33.8%
CDKN2A	p.E88fs Frameshift - LOF	30.1%
KMT2D	p.Q2634* Stop gain - LOF	17.7%
ARID1A	p.S334* Stop gain - LOF	13.2%
RNF43	p.M1? Start loss - LOF	9.4%
CCNE1	Copy number gain	
LRP1B	Copy number loss	
PHGDH	Copy number gain	

Germline - Pathogenic / Likely Pathogenic

No germline pathogenic variants were found in the l[illegible]ed set of [illegible]enes on which we report.

Pertinent Negatives

No pathogenic single nucleo[illegible]e va[illegible]nts, inde[illegible] or copy number changes found in:

EGFR | KRAS | BR[illegible] | ALK | ROS1 | RET | MET | ERBB2 (HER2)

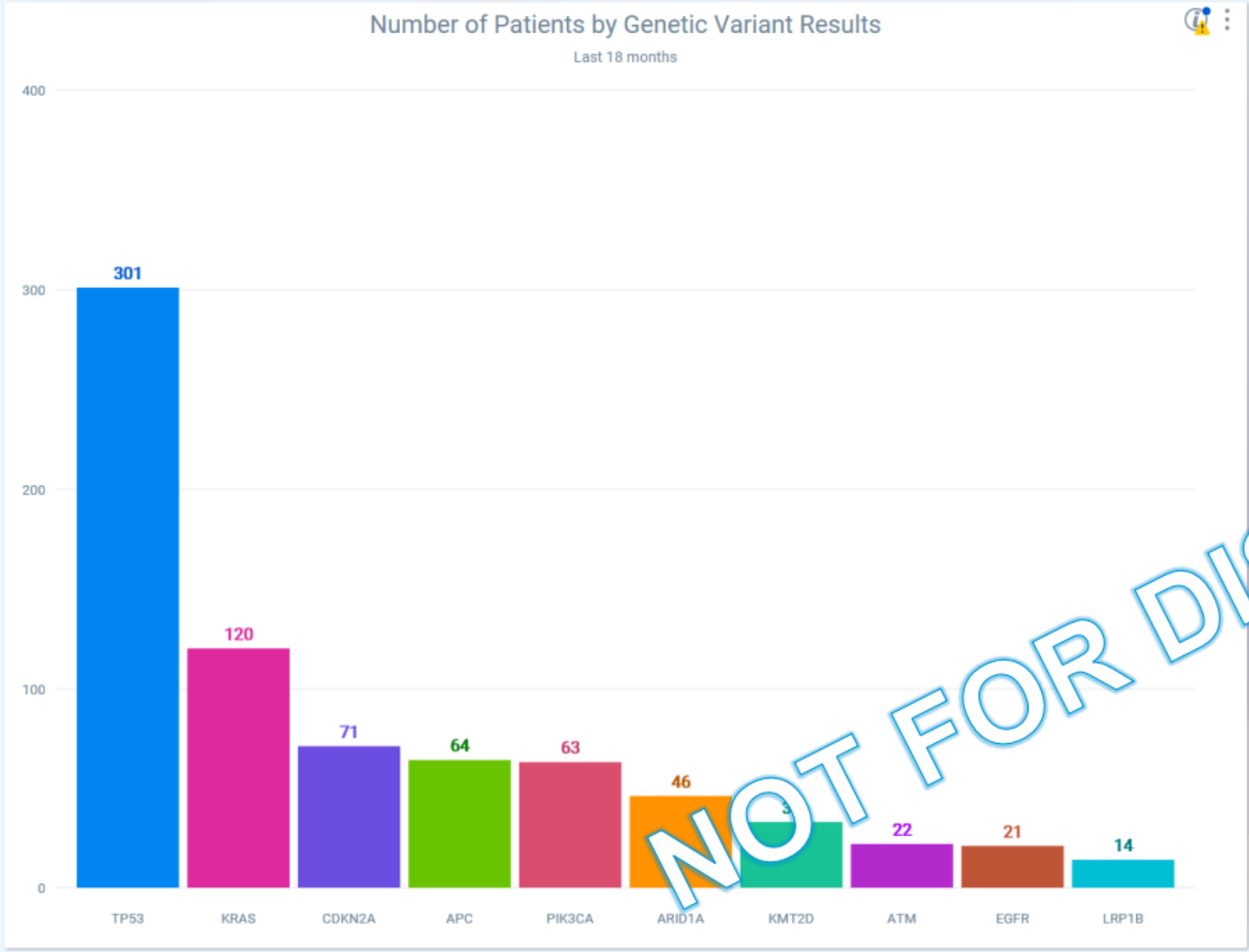
I[illegible]MUNOTHERAPY MARKERS

Tum[illegible]r Mutational Burden: 14.7 m/MB — 93rd percentile

Microsatellite Instability Status: **Stable** | Equivocal | High

CogitoSlicerDicer

About Undo Redo Start Over Load Save As Share Troubleshoot Settings Tutorials



Population

Base: All Patients

Slices

10 Slices by Genetic Variant Results

Measures

Number of Patients

Dates

Start Date: Aug 15, 2021
End Date: Feb 14, 2023
Slice By: None

Visual Options

Bar Color:

Slice by Genetic Variant Results

Grab Top 10

TP53
Clinical Significance Any
Pathogenic
Assessment Any
Genomic Source Any
Is Amplification Any
KRAS
CDKN2A
KMT2D
ATM
EGFR
LRP1B

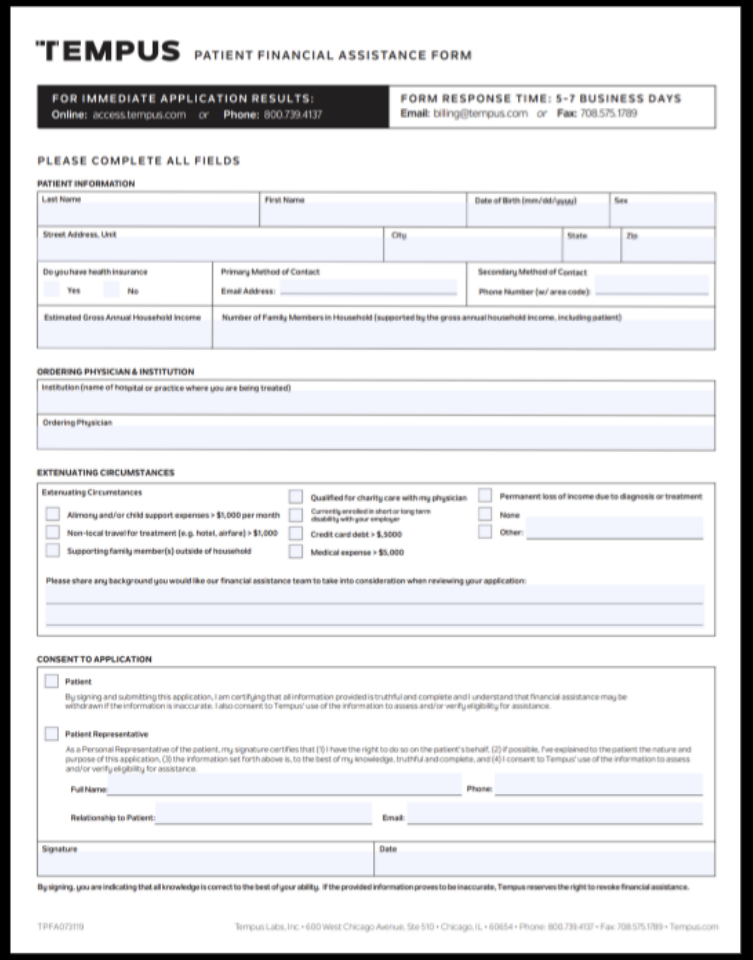
Compare t

Hyperspace - NOMC HEREDITARY A
CLINIC BENSON - prd - \\Remote

Patient Financial Assistance

Tempus submits to insurance and applies Financial Assistance Program.

The majority of patients pay <$100 OOP for testing.



TEMPUS PATIENT FINANCIAL ASSISTANCE FORM

FOR IMMEDIATE APPLICATION RESULTS:
Online: access.tempus.com or Phone: 800.739.4137

FORM RESPONSE TIME: 5-7 BUSINESS DAYS
Email: billing@tempus.com or Fax: 708.575.1789

PLEASE COMPLETE ALL FIELDS

PATIENT INFORMATION

Last Name | First Name | Date of Birth (mm/dd/yyyy) | Sex

Street Address, Unit | City | State | Zip

Do you have health insurance: Yes No | Primary Method of Contact: Email Address: | Secondary Method of Contact: Phone Number (w/ area code):

Estimated Gross Annual Household Income | Number of Family Members in Household (supported by the gross annual household income, including patient)

ORDERING PHYSICIAN & INSTITUTION

Institution (name of hospital or practice where you are being treated)

Ordering Physician

EXTENUATING CIRCUMSTANCES

Extenuating Circumstances

- Alimony and/or child support expenses > $1,000 per month
- Non-local travel for treatment (e.g. hotel, airfare) > $1,000
- Supporting family member(s) outside of household
- Qualified for charity care with my physician
- Currently enrolled in short or long term disability with your employer
- Credit card debt > $5,000
- Medical expense > $5,000
- Permanent loss of income due to diagnosis or treatment
- None
- Other:

Please share any background you would like our financial assistance team to take into consideration when reviewing your application:

CONSENT TO APPLICATION

Patient

By signing and submitting this application, I am certifying that all information provided is truthful and complete and I understand that financial assistance may be withdrawn if the information is inaccurate. I also consent to Tempus' use of the information to assess and/or verify eligibility for assistance.

Patient Representative

As a Personal Representative of the patient, my signature certifies that (1) I have the right to do so on the patient's behalf, (2) if possible, I've explained to the patient the nature and purpose of this application, (3) the information set forth above is, to the best of my knowledge, truthful and complete, and (4) I consent to Tempus' use of the information to assess and/or verify eligibility for assistance.

Full Name: Phone:

Relationship to Patient: Email:

Signature | Date

By signing, you are indicating that all knowledge is correct to the best of your ability. If the provided information proves to be inaccurate, Tempus reserves the right to revoke financial assistance.

TPFA073119

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- All patients should apply
- Real time decision online or by phone
- 3 Ways to apply:
  - access.tempus.com
  - By calling 1-800-739-4137
  - Paper Form submitted in kit or faxing to 1-(708)-575-1789
- Cash Pay:
- Domestic $649
- International $2500

Patient Financial Assistance Program

Tempus is committed to help provide access to our tests for patients in financial need:

- All patients treated in the U.S. are eligible
- Most applicants who qualify pay no more than $100

How to apply:

- access.tempus.com
- 800-739-4137
- Financial Assistance Form

TEMPUS PATIENT FINANCIAL ASSISTANCE FORM

FOR IMMEDIATE APPLICATION RESULTS:
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FORM RESPONSE TIME: 5-7 BUSINESS DAYS
Email: billing@tempus.com or Fax: 708.575.1789

PLEASE COMPLETE ALL FIELDS

PATIENT INFORMATION

Last Name	First Name	Date of Birth (mm/dd/yyyy)	Sex

Street Address, Unit	City	State	Zip

Do you have health insurance: Yes No	Primary Method of Contact: Email Address:	Secondary Method of Contact: Phone Number (w/ area code):

Estimated Gross Annual Household Income	Number of Family Members in Household (supported by the gross annual household income, including patient)

ORDERING PHYSICIAN & INSTITUTION

Institution (name of hospital or practice where you are being treated)
Ordering Physician

EXTENUATING CIRCUMSTANCES

Extenuating Circumstances

- ☐ Alimony and/or child support expenses > $1,000 per month
- ☐ Non-local travel for treatment (e.g. hotel, airfare) > $1,000
- ☐ Supporting family member(s) outside of household
- ☐ Qualified for charity care with my physician
- ☐ Currently enrolled in short or long term disability with your employer
- ☐ Credit card debt > $5,000
- ☐ Medical expense > $5,000
- ☐ Permanent loss of income due to diagnosis or treatment
- ☐ None
- ☐ Other: _____

Please share any background you would like our financial assistance team to take into consideration when reviewing your application:

CONSENT TO APPLICATION

☐ Patient

By signing and submitting this application, I am certifying that all information provided is truthful and complete and I understand that financial assistance may be withdrawn if the information is inaccurate. I also consent to Tempus' use of the information to assess and/or verify eligibility for assistance.

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Full Name: _____ Phone: _____

Relationship to Patient: _____ Email: _____

Signature	Date

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Didactic Q & A

LOUISIANA SESSION 5

Case Presentation: Ochsner LSU Health Feist-Weiller Cancer Center

Kavitha Beedupalli

Associate Professor – Clinical

Case Summary:

- 60 yo African American man with around 50 Pack year history of smoking
- Underwent scans for evaluation of back pain
- Ct scan showed a Large left perihilar mass- 9.8x 4.8cms with extensive mediastinal, bilateral hilar, supraclavicular adenopathy, Right first rib, large Rt scapular lesion , T9 and T11 vertebral lesions
- Imaging with pathological fracture with cord compression at T9 vertebral level requiring surgical decompression
- Pathology showed metastatic Adenocarcinoma of pulmonary origin
- The tumor cells show diffuse positivity for Cytokeratin 7, Keratin AE1/3, patchy nuclear positivity for TTF1 and Napsin

Section 3: Patient-Level Case Presentation

DEMOGRAPHIC INFORMATION			
1. **Age**	2. **Gender (*Choose One*)**	3. **Race/Ethnicity (*Choose All that Apply*)**	
60	Female☐ Male☒ Non-Binary/Third gender☐ Transgender female☐ Transgender male ☐	American Indian/Alaska Native ☐ Asian ☐ Black/African American ☒	Hispanic/Latino ☐ White ☐ More than One Race ☐ Other ☐

NON-SMALL CELL LUNG CANCER (NSCLC) HISTOLOGY & STAGE		
4. **Diagnosis**	5. **Histology**	6. **Stage**
Initial Diagnosis ☒ Recurred and or Progressed ☐	Adenocarcinoma ☒ Squamous Cell ☐ Large Cell ☐	Stage IV –T4 N3M1C

BIOMARKER TESTING	
7. **Has biomarker testing been ordered for this patient (or will it be ordered)?**	8. **If biomarker testing was not ordered, please elaborate on the factors that precluded it:**
Yes ☒ No ☐ Will be ordered ☐	Click or tap here to enter text.

The next section is ONLY for those patients who HAVE received or WILL receive biomarker testing

9. **Which technique was used (or will be used) to obtain specimen for pathologic diagnosis? *(Choose One)***	
Bronchoscopic biopsy ☐ Endobronchial ultrasound-guided transbronchial lymph node aspiration (EBUS-TBNA) ☐ Image-guided percutaneous biopsy ☐ Liquid biopsy ☐	Mediastinoscopy ☐ Surgical specimen ☒ Thoracentesis/pericardiocentesis ☐ Unsure ☐

10. **Which platform was/will be used for lung biomarker testing? *(Choose One)***	11. **If single-gene test or short-cluster panel, please identify which genes were tested:**		
Single-Gene Test ☐ Short-Cluster Panel ☐ Multi-Gene Panel (next generation sequencing (NGS) ☒	ALK ☐ BRAF ☐ EGFR ☐	HER2 ☐ KRAS ☐ NTRK ☐ MET ☐	PD-L1 ☐ ROS1 ☐ RET ☐

ADDITIONAL INFORMATION
12. **Please include any other information you would like to share with the group:** Click or tap here to enter text.

Additional Challenges/Barriers for the Patient:

Patient education, delay in initiation of treatment, transportation issues

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

Involving nurse navigator/social worker early on has helped with this

What data do you have to augment your observations:

Case Presentation Discussion

Discussion/Feedback from our Faculty

Wrap-Up & Post-Session Poll Questions

A Few Reminders

<u>Final</u> ECHO Session: May 2023 – Look for invite coming soon!

Next Didactic Presenter: TBD
Topic: TBD

Materials and Resources will be made available soon. All resources will be available on the [ACS ECHO Website]

Spokes: Interested in presenting a Case in May? Let us know.
Faculty: All future case presentations will be shared with you at least 24-hours in advance

Additional Feedback on Today's Session? Tell us in the Post Session Feedback Forum
(URL in chat box)

Questions: Contact Leigh Davis

Thank you to Amgen for their generous support!

SEE YOU AT SESSION 6!