MaTOS™
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Health Care Disparities in Lung Cancer Genomic Profiling: Has Precision Oncology Widened the Gap?

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Accelerated Biomarker Discovery: Driving Targeted Therapy Advancements and Biomarker Testing Demand

First Cancer Biomarker

Immunoglobulin Light Chain Identified in Urine of a Patient with Multiple Myeloma[1,2]

Genomic Technological Advancements

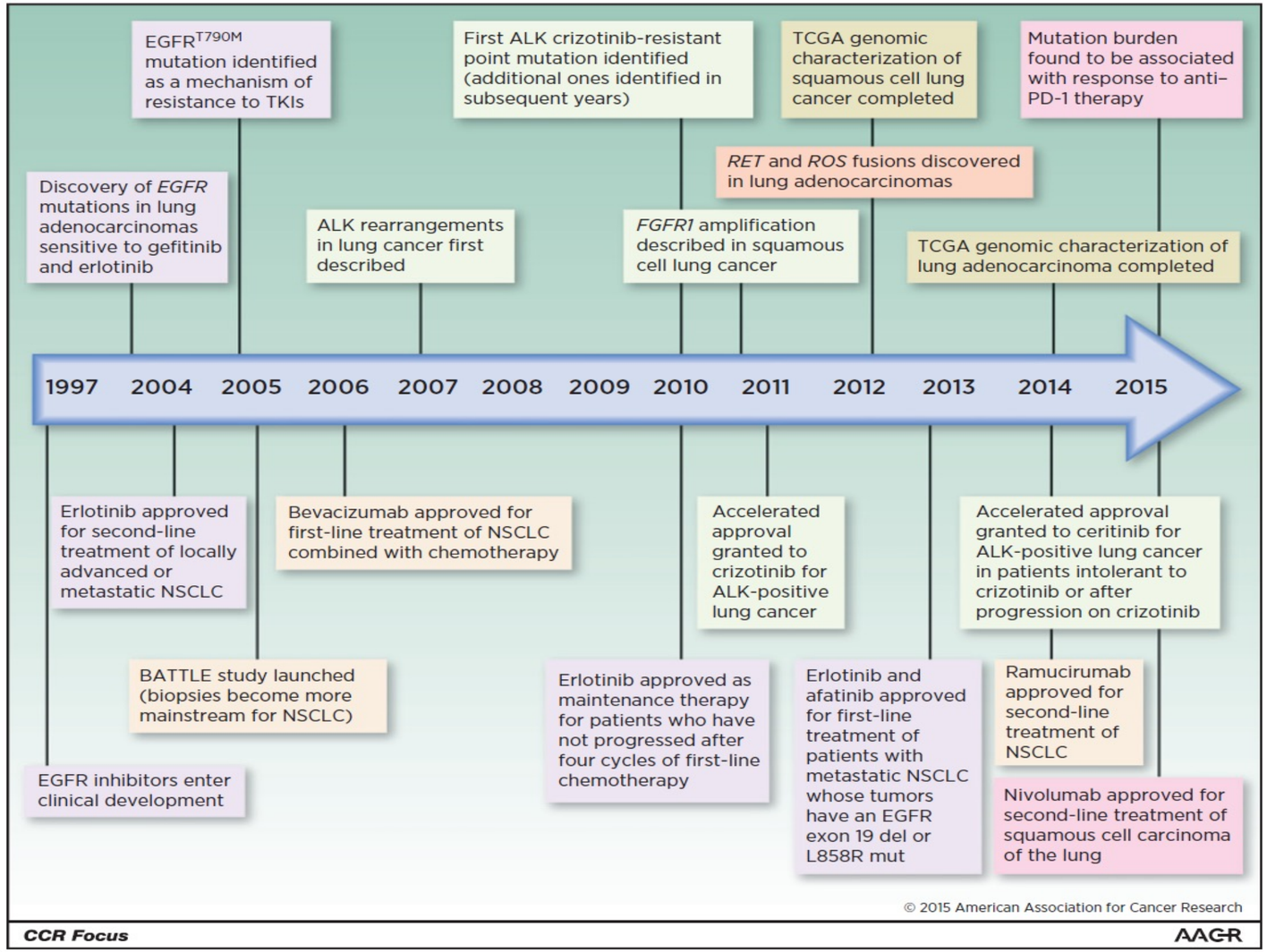
Genomic Technology Advancements Accelerate Biomarker Identification and Characterization

Precision-Based Targeted Therapies

Enhanced Biomarker Understanding Drives Precision Therapies, Improving Cancer Patient Outcomes

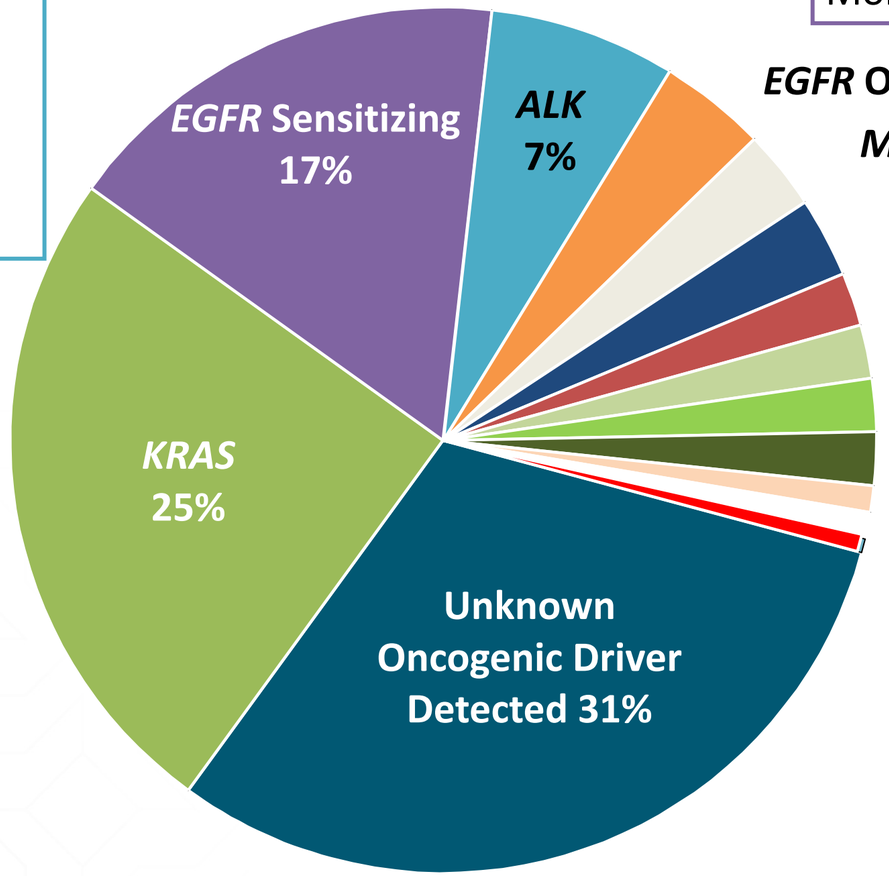
Increased Need for Biomarker Testing

Surge in Targeted Therapies Spurs Biomarker Testing Demand



1. Hadju SJ. *Ann Clin Lab Sci*. 2006;36(2):222-223; 2. Bence Jones H. On a new substance occurring in the urine of a patient with “mollities ossium.” *Philos Trans* 1848; 138:55–62; 3. Polti K, et al. *Clin Cancer Res.* 2015;21(10):2213-2220.

Increased complexity of genomic alterations is expanding treatment options



ALK:
Crizotinib
Alectinib
Ceritinib
Lorlatinib
Brigatinib

KRASG12C
Sotorasib
Adagrasib

***EGFR* Sensitizing:**
Gefitinib
Erlotinib
Afatinib
Osimertinib
Dacomitinib

***EGFR 20ins*:**
Amivantamab
Mobocertinib

***EGFR* Other 4%**

***MET* 3%**

> 1 Mutation 3%

***HER2* 2%**

***ROS1* 2%**

***BRAF* 2%**

***RET* 2%**

***NTRK1* 1%**

***PIK3CA* 1%**

***MEK1* < 1%**

***MET*ex14:**
Capmatinib/Tepotinib

***ROS1*:**
Crizotinib
Entrectinib

***BRAF* V600E:**
Dabrafenib/Trametinib
Encorafenib/Binimetinib

***RET* fusion:**
Selpercatinib
Pralsetinib

***NTRK* fusion:**
Entrectinib
Larotrectinib

Li. JCO. 2013;31:1039. Tsao. J Thorac Oncol. 2016;11:613.
Slide credit: clinicaloptions.com

The Gentrification of Lung Cancer Treatment

When I completed fellowship

Today

- **Chemo+/- Bevacizumab**
- **Erlotinib**
- **Hospice**

Brickell Avenue, Miami

$60/sqft→ $666/sqft

- **Chemo-Immuno**
- **Immunotx**

- **Targeted Therapies:**

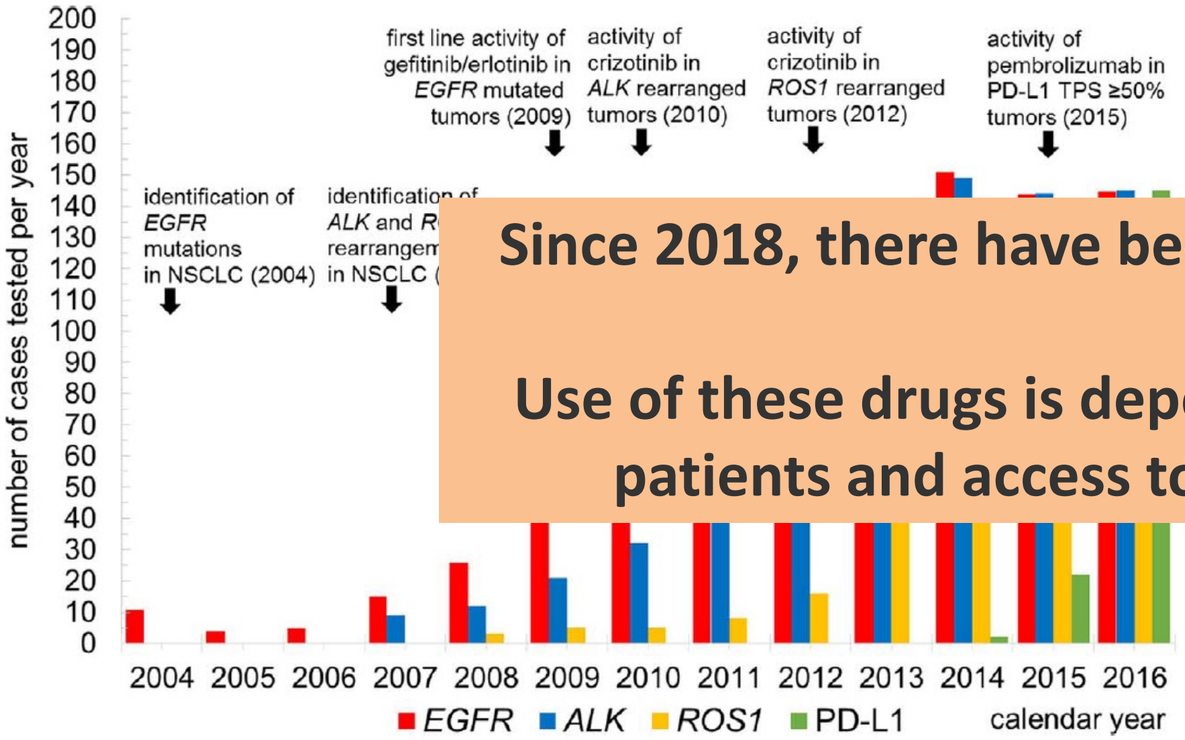
✓EGFR
✓ALK
✓ROS
✓BRAF V600E
✓Met Ex 14 Skip
✓RET
✓KRASG12C
✓ERBB2
✓NTRK

With more Complexity in Testing & Treatment ,

There is more Room for Disparities

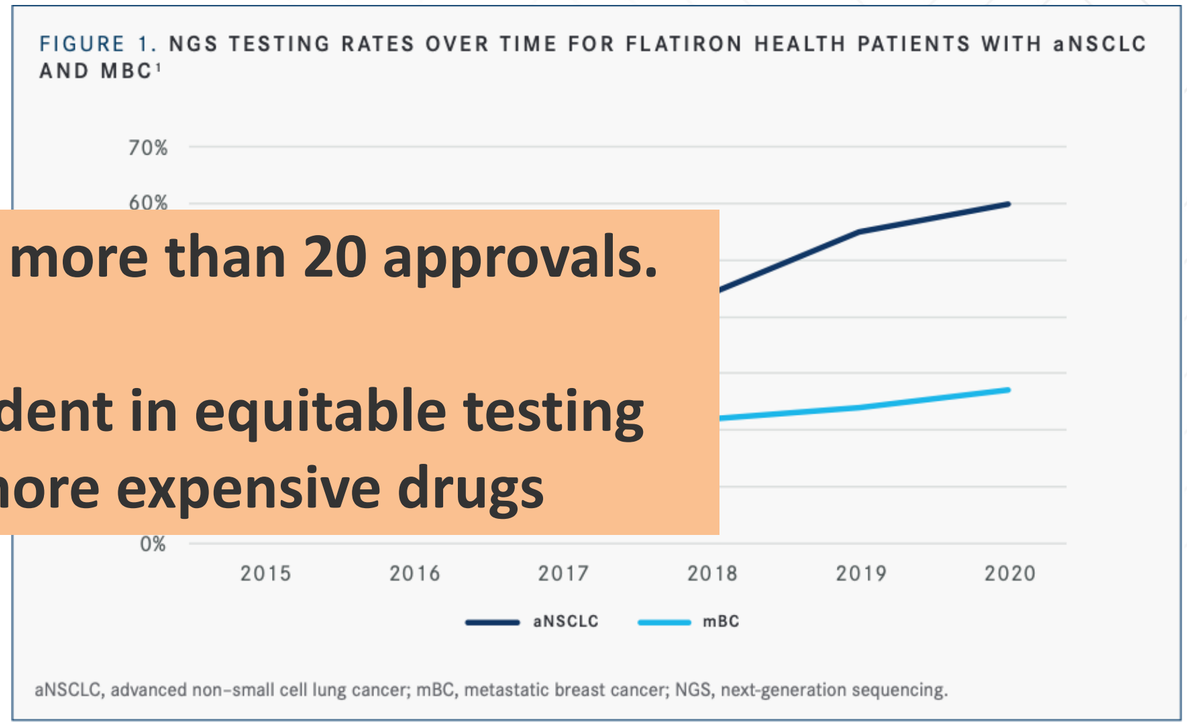
Increasing Biomarker Testing Volumes in Lung Cancer

Annual Biomarker Testing Volumes in Advanced NSCLC



Since 2018, there have been more than 20 approvals.

Use of these drugs is dependent in equitable testing patients and access to more expensive drugs



VanderLaan PA, et al. *Lung Cancer.* 2018;116:90-95.

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Biomarker Testing Rates: MYLUNG

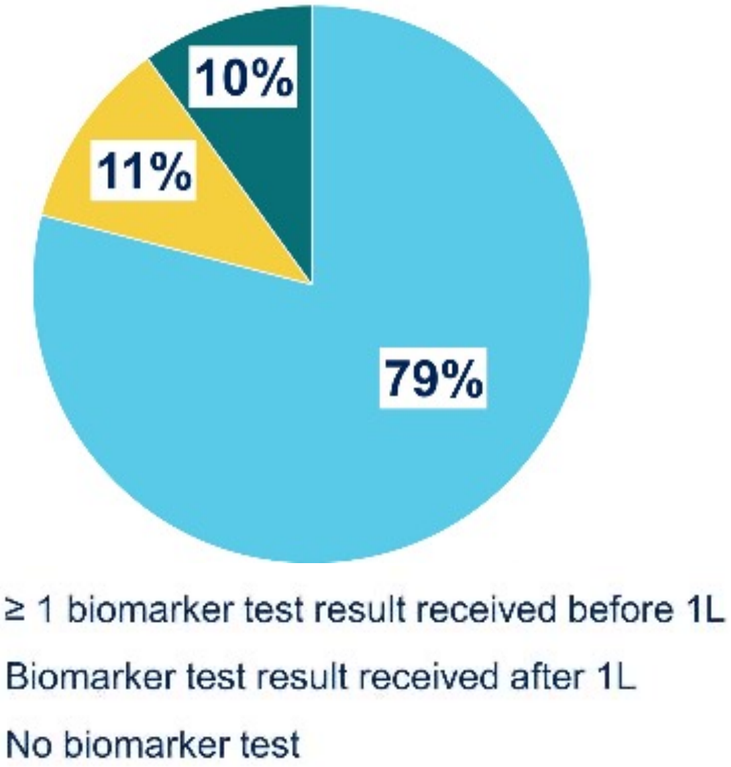
(Molecularly Informed Lung Cancer Treatment in a Community Cancer Network)

Test types	Overall N=3474	Nonsquamous N=2820
EGFR	70%	76%
ALK	70%	76%
ROS1	68%	73%
BRAF	55%	59%
PD-L1	83%	83%
Any biomarker	90%	91%
All 5 biomarker tests	46%	49%
NGS	37%	39%

Retrospective single-institution study of pts w/ newly diagnosed stage IV non-Sq NSCLC (N=335)[2]

- **Disparities in comprehensive biomarker testing**
- **18%-39% of patients began treatment before receiving molecular profiling results**

Testing Relative to 1L Treatment Initiation

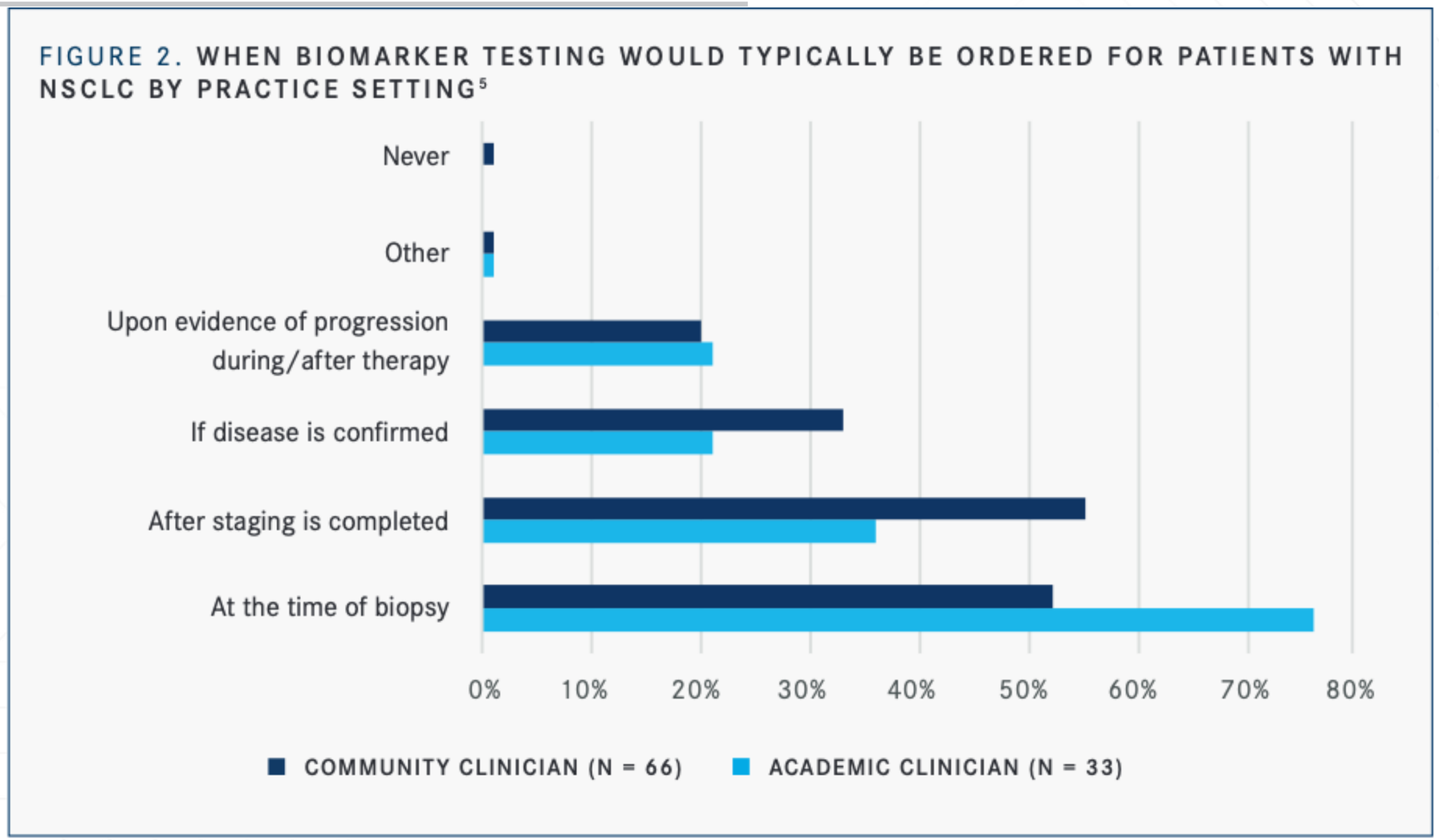


Pts w/ mNSCLC initiating 1L systemic therapy between 04/01/2018 and 03/31/2020 (n=3474)[1]

- Patients with comprehensive genotyping have improved OS compared to patients with incomplete or no testing.

1. Robert NJ, et al. ASCO 2021. Abstract 9004. 2. Aggarwal C, et al. ASCO 2022. Abstract 9022.

Testing Disparities: Community vs Academic Centers



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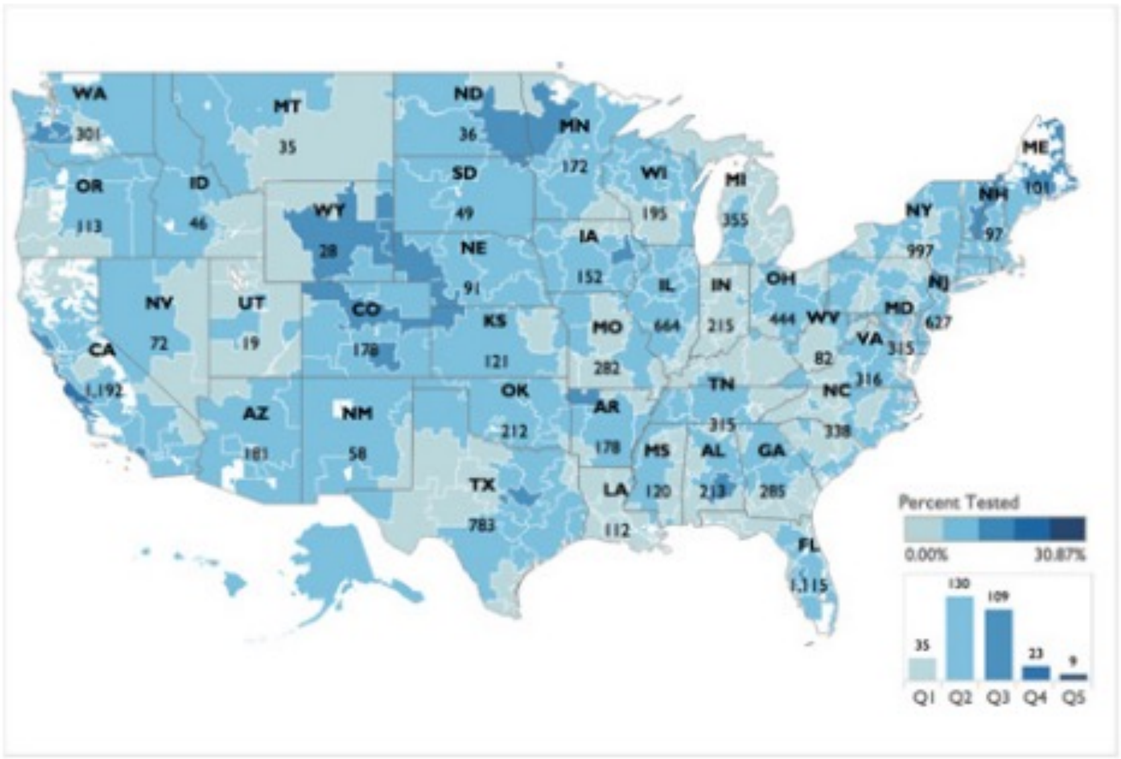
Disparities in Access to Molecular Testing is Multifactorial

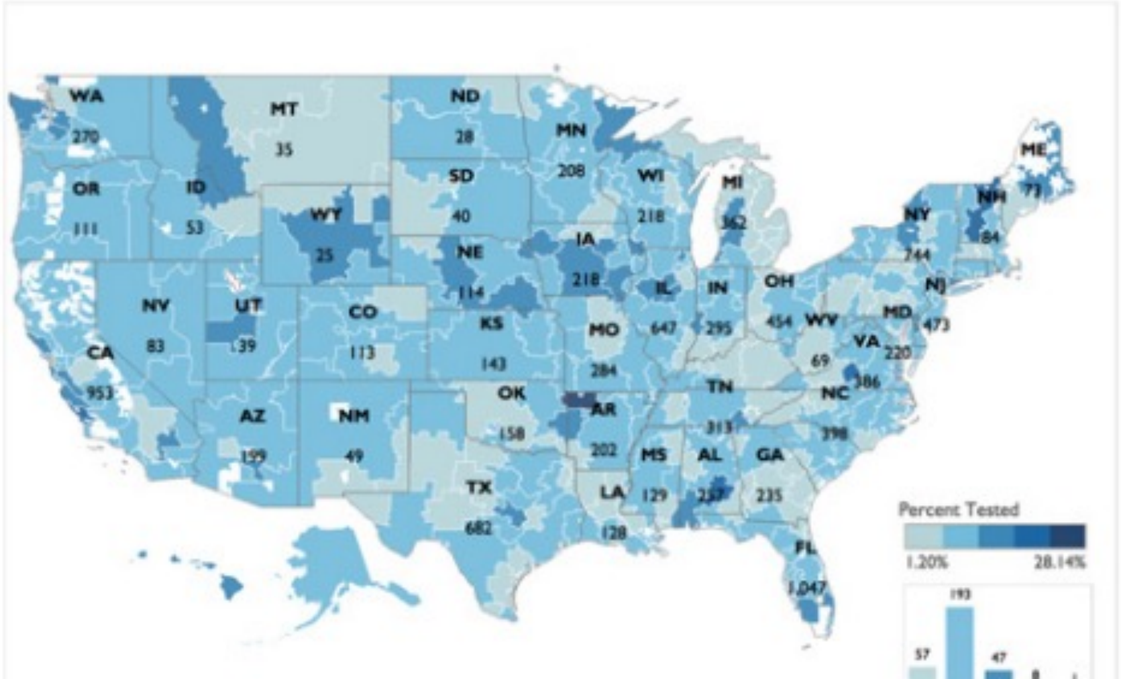
RESEARCH ARTICLE Open Access

Underutilization and disparities in access to *EGFR* testing among Medicare patients with lung cancer from 2010 – 2013

Julie A. Lynch[1,7*], Brygida Berse[2,3], Merry Rabb[4], Paul Mosquin[4], Rob Chew[4], Suzanne L. West[4], Nicole Coomer[4], Daniel Becker[5,6] and John Kautter[2]

- Medicare claims data 2010-2013
- Geographic area most strongest predictor
- Race predictor (Blacks less likely, Asians more likely)
- Distance from a NCI Cancer Center
- Zip cide and built environment





Lynch et al. BMC Cancer (2018) 18:306

Racial disparities in biomarker testing and clinical trial enrollment

- **Real World Practice Cohort (Flatiron)**
  - N=14,768 Stage IV NSCLC
  - Diagnosed 1/2017-10/2020
  - Treated within 120 days of diagnosis

- Black patients less likely to get NGS biomarker testing (39% vs 50% NHWs)

- Participation in clinical trials higher in pts getting NGS

Bruno et al. Presented at ASCO 2021. Abstract 9003.

Biomarker Testing

All patients with NSCLC				
	NSCLC overall N=14,768	White N=9,793	Black/AA N=1,288	P-value, White vs Black/AA
Ever tested	11,297 (76.5%)	**7477 (76.4%)**	**948 (73.6%)**	**0.03**
Tested prior to first line therapy		6,064 (61.9%)	784 (60.9%)	0.47
Ever NGS tested	7,185 (48.7%)	**4,904 (50.1%)**	**513 (39.8%)**	**<0.0001**
NGS tested prior to first line therapy		**3,081 (31.5%)**	**332 (25.8%)**	**<0.0001**
Patients with non-squamous NSCLC				
	Non-squamous N=10,333	White N=6,705	Black/AA N=922	P-value, White vs Black/AA
Ever tested	8,786 (85.0%)	5,699 (85.0%)	764 (82.9%)	0.09
Tested prior to first line therapy		4,881 (72.8%)	662 (71.8%)	0.52
Ever NGS tested	5,494 (53.2%)	**3,668 (54.7%)**	**404 (43.8%)**	**<0.0001**
NGS tested prior to first line therapy		**2,452 (36.6%)**	**274 (29.7%)**	**<0.0001**

AA = African American; NGS = next-generation sequencing

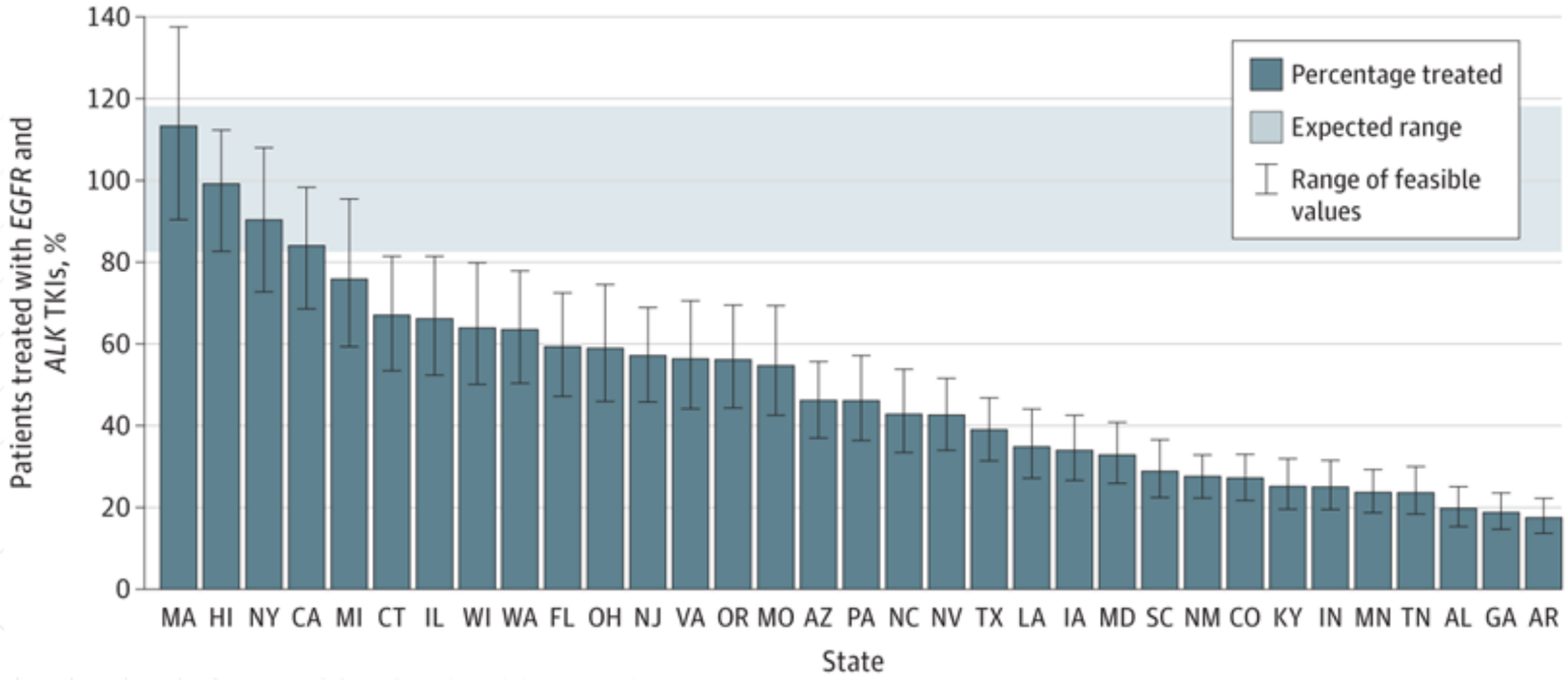
Clinical Trial Participation, Logistic Regression

Among Patients who were Black/African American (AA) and White - overall NSCLC

Variable	Odds ratio (95% CI)	P-value
Biomarker testing before start of first-line therapy (yes vs no)	2.29 (1.64-3.20)	<0.0001
Ever NGS (yes vs no)	2.41 (1.56-3.70)	<0.0001
Race (Black/AA vs White)	0.45 (0.26-0.79)	0.005

Among all covariates evaluated, the additional factors associated with clinical trial participation among Black and White patients included: age at diagnosis, histology, stage III vs IV, and practice volume

Osimertinib or Alectinib Use by State Medicaid Programs, Compared With Expected Levels of Use, 2020-2021



- Est **66%** of patients with *EGFR*- and *ALK*-altered metastatic disease received indicated targeted therapies across all states
- Rates of targeted therapy use ranged from **18%** (Arkansas) to **113%** (Massachusetts)
- **91%** of states had lower rates of targeted therapy use than expected

Robert, et al. *JAMA Netw Open.* 2023;6(1):e2252562

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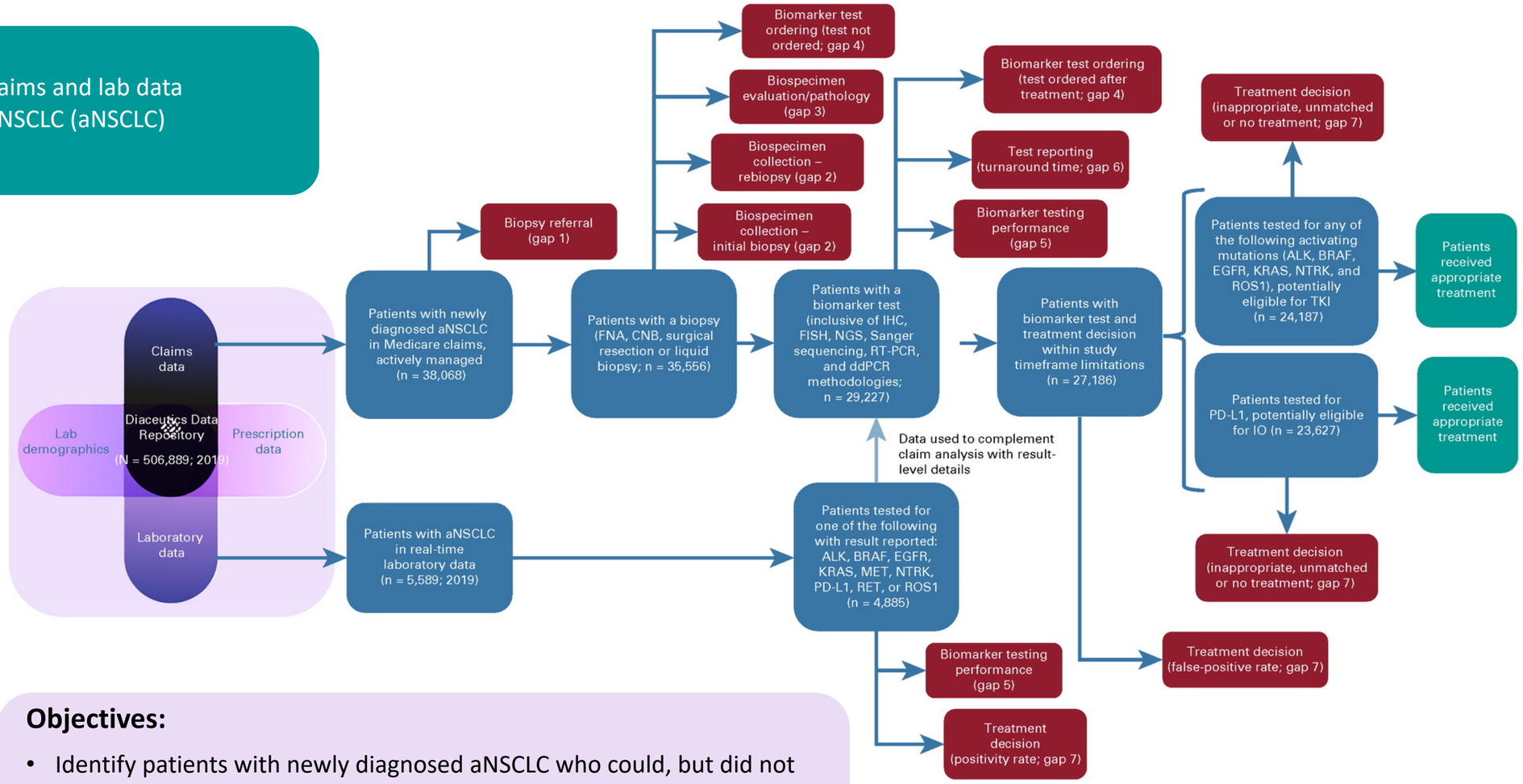
Real World Data Analysis of Patients Lost at Each Step of the Precision Oncology Pathway

Diaceutics' Data Repository
- Commercial and Medicare claims and lab data
- Newly diagnosed, advanced NSCLC (aNSCLC)
- N = 506,889

49.7% of patients lost to factors related to biomarker testing

Of patients who received biomarker testing, **29.2%** did not receive appropriate targeted treatments

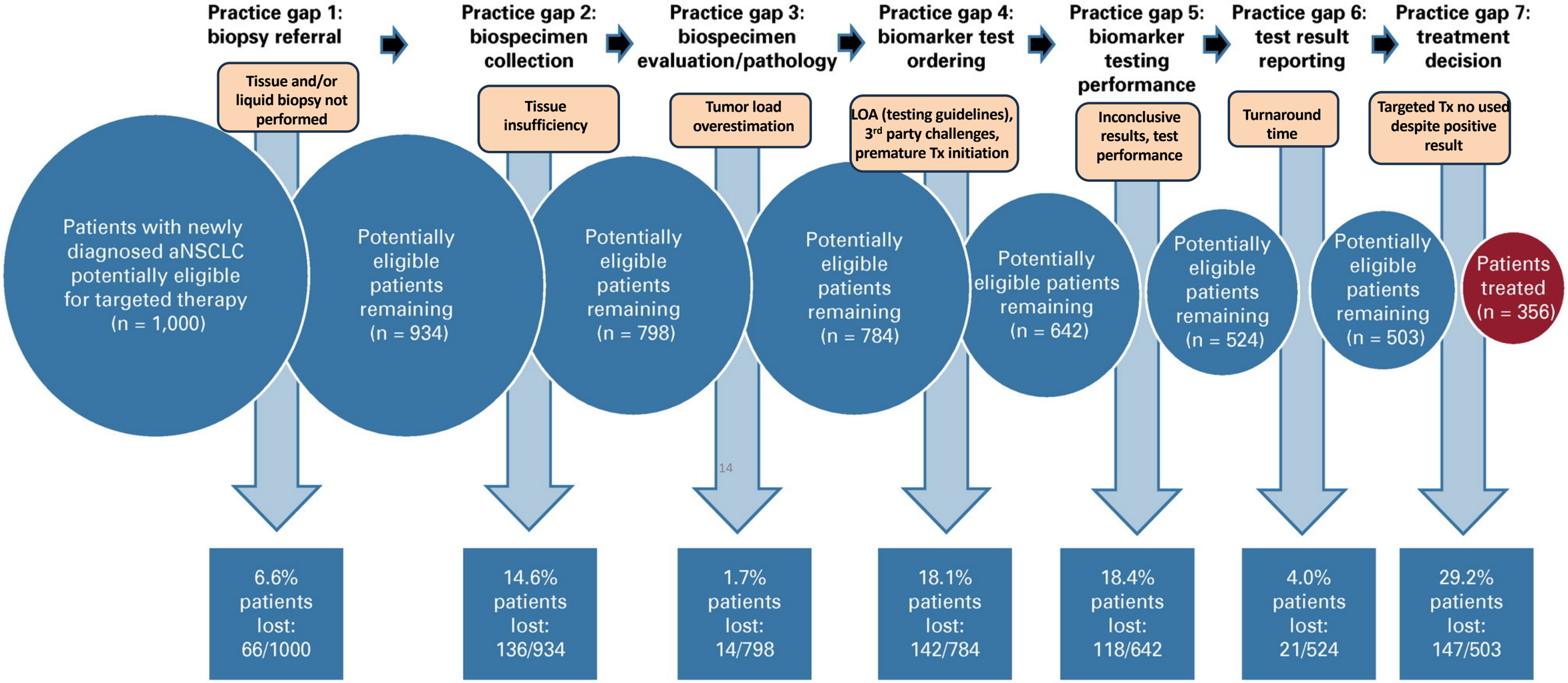
~64% of potentially eligible patients with aNSCLC not benefiting from precision oncology therapies



Objectives:
- Identify patients with newly diagnosed aNSCLC who could, but did not benefit from a personalized treatment.
- Examine clinical practice gaps in the delivery of precision oncology care from diagnosis to treatment.

Sadik, H, et al. *JCO Precision Oncol.* 2022;6:e2200246.

Clinical Practice Gaps with Biomarker Testing in Advanced NSCLC



Approximately **50% of patients** are lost in precision oncology due to gaps in biospecimen processing and diagnostic testing

Sadik, H, et al. *JCO Precision Oncol.* 2022;6:e2200246.

IASLC: Barriers to Biomarker Testing

Timing

- **Turnaround time requesting and treating respondents**
  - ≥10 days – 29% (highest % in North America)
- **Turnaround time performing and interpreting assay respondents**
  - 0 to 5 days - **29%**
  - 6 to 10 days – **53%**
  - 11 to 15 days – **16%**
  - >15 days – **2%**

Awareness

- **~33%** unaware of most recent testing guidelines
- **75%** hold multidisciplinary tumor boards to discuss cases

Access

- **Molecular testing:**
- In-house laboratories – **30%**
- Completely outsource – **43%**
- Partially in-house and partially outsource – **28%**

Quality

- Insufficient tumor cells – **83%**
- Inadequate tissue quality – **55%**
- Lack of sensitivity of assay or assay use failure – **18%**
- Inadequate technical laboratory expertise – **10%**

Cost

- Direct patient pay - **44 – 63%**
- Public/government support – **40 – 61%**
- Pharmaceutical company sponsorship – **29%**
- Private insurance – **16 -27%**

Hess, LM, et al. *JTO Clinical and Research Reports.* 2022;3(6):100336.

How to Address Disparities in Testing

1. Advocate for Legislation for Universal coverage of guideline-recommended biomarker tests
2. Ensuring coverage of biomarker testing for all patients – including those insured through Medicaid
3. Uniform Payer Coverage Policies of Tumor Biomarker Testing
4. Guidelines for Uniform Testing & Reporting of Results
5. Talk to your Institution about Reflex Testing- Simplify the Process

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Thank You

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