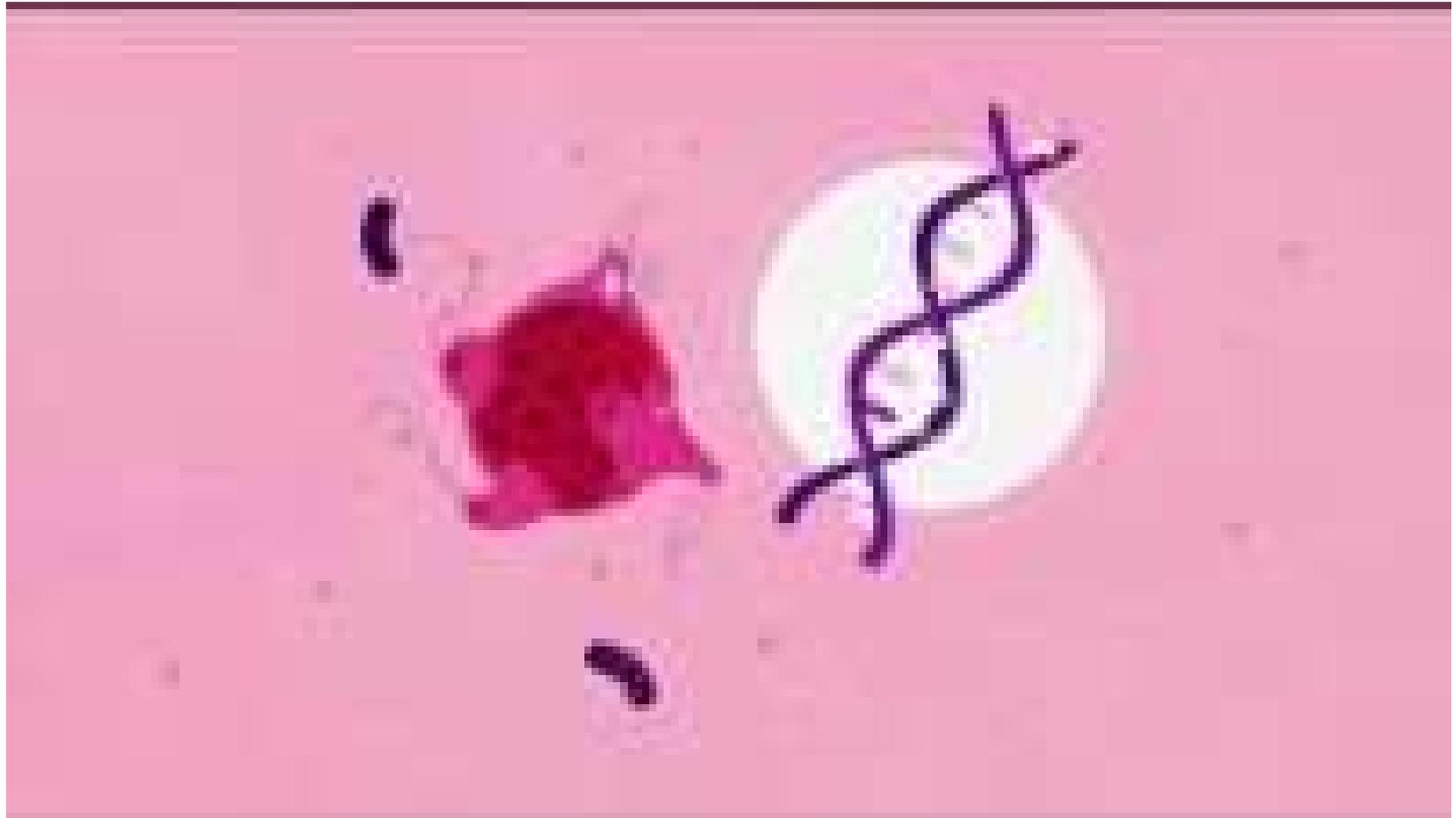


Biomarkers and Precision Medicine

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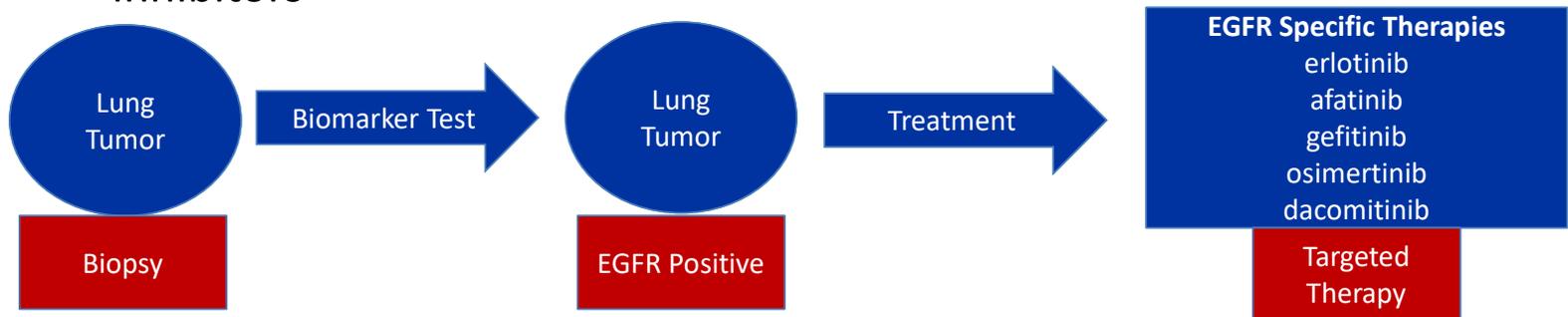
Biomarkers and Precision Medicine

- Biomarkers - a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention
- Biomarkers include but are not limited to gene mutations or protein expression
- An essential component of precision medicine connecting the **right patient** to the **right treatment** at the **right time**
 - Targeted cancer therapy
 - Avoidance of therapies unlikely to provide clinical benefit



What is Biomarker Testing?

- **Biomarker Testing in People with Cancer**
 - Looks for the presence of molecules like proteins or gene mutations found in cancer cells
 - Can be used to inform therapy selection
 - Example: EGFR-positive non-small cell lung cancer --> several EGFR inhibitors



- Being explored in a variety of disease areas (e.g., cardiology, rheumatology, neurology, infectious diseases, respiratory, autoimmune)

Biomarker Testing and Clinical Trials

- Biomarker testing provides value beyond therapy selection, and results from testing can be utilized to inform patients of relevant clinical trial opportunities
- Cancer clinical trials are increasingly driven by biomarkers and the development of targeted therapies
 - From 15% in 2000 to 55% in 2018¹



[1] The Evolution of Biomarker Use in Clinical Trials for Cancer Treatment Key Findings and Implications. Personalized Medicine Coalition 2019.

Trends in Biomarker Usage

Nearly 80 oncology medicines are used after a predictive biomarker test up from 20 in 2011

Exhibit 38: Number of U.S. Oncology Medicines with Required or Recommended Predictive Biomarker Testing



Source: IQVIA Institute, May 2021

Who Should Get Tested and Why?

The Role of Clinical Guidelines in Determining Appropriate Testing

- Several professional associations have cancer biomarker testing and treatment guidelines
 - National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology, American Society of Clinical Oncology (ASCO), others
 - One way to assure that testing and treatment take advantage of the latest knowledge
- Biomarker testing has become the standard of care in certain cancers
- **Patients who receive biomarker testing and are eligible for and receive targeted cancer therapy have better outcomes.**



Biomarker-driven Therapy Improves Outcomes

- Target therapy vs. chemotherapy (NSCLC)
 - Targeted therapy group lived **1.4 years longer**¹
- Targeted therapy vs. non-targeted (NSCLC)
 - **31 percent reduction in risk of death** and improved survival that was about 1.5-fold longer²
- Targeted therapy vs. non-targeted (diverse metastatic cancers)
 - **Two-fold increase** in median progression free survival³
 - **One- and one-half fold increase** in overall survival³

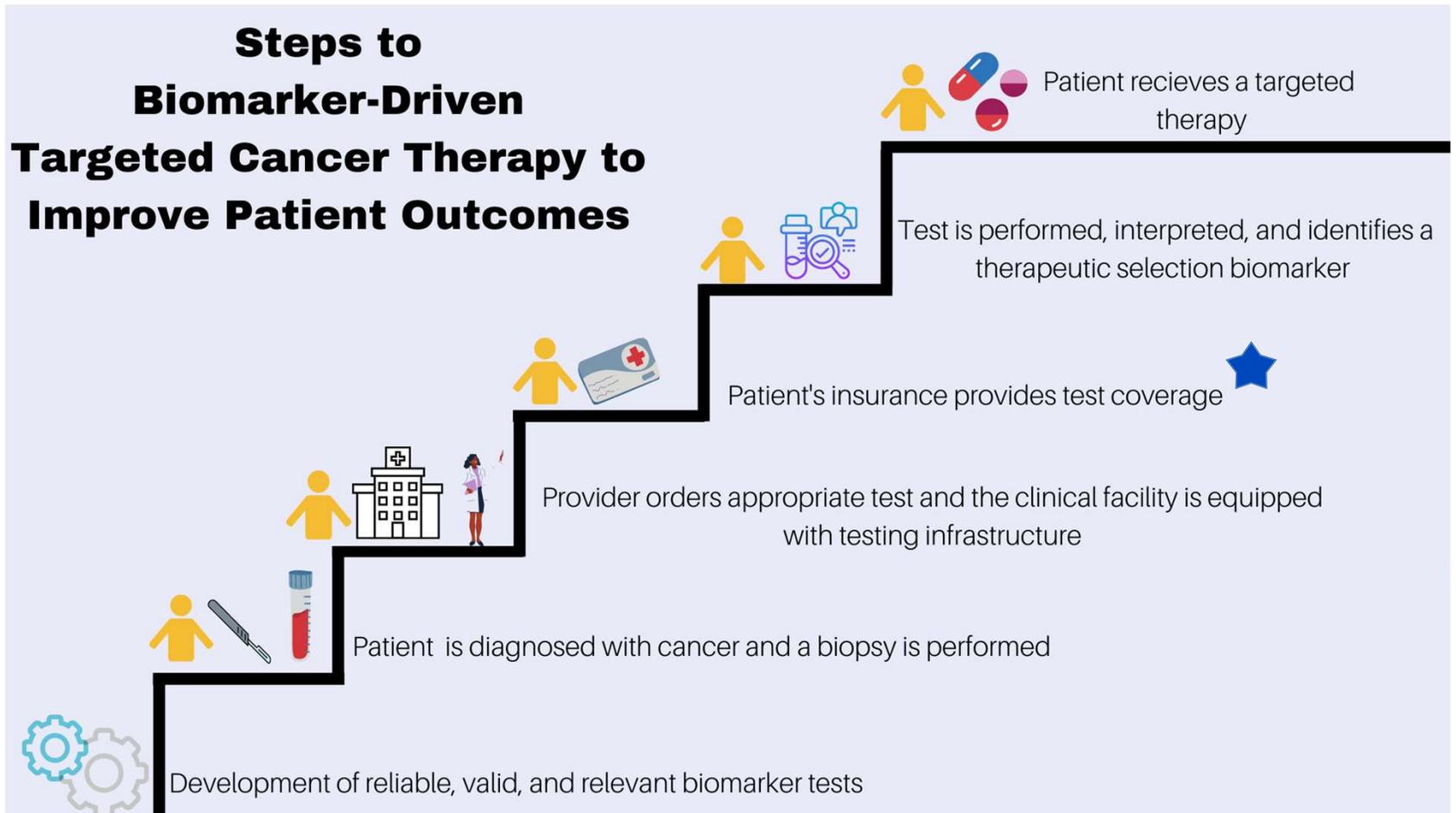


[1] Gutierrez, 2017

[2] Kris MG, et al., 2014

[3] Schwaederle, 2015

Barriers to Cancer Biomarker Testing



Barriers to Cancer Biomarker Testing

- Coverage of tests differs greatly across payers
- Coverage policies generally more common for single-gene tests vs. multi-gene panel tests
 - **Commercial plan coverage policies for multi-gene panel tests are frequently more restrictive than what is recommended in NCCN clinical guidelines¹**
 - Panel tests can make more efficient use of a tissue sample compared to multiple single-gene tests
- **Health Equity:** patients who are older, Black, uninsured, or Medicaid-insured, or live in rural areas are less likely to be tested for certain guideline-indicated biomarkers^{2,3,4}
- Differential access can potentially widen existing disparities in cancer outcomes.



[1] Wong, W., et al. (2022) *Alignment of health plan coverage policies for somatic multigene panel testing with clinical guidelines in select solid tumors.*

[2] Presley, C., et al. (2017). *Disparities in next generation sequencing in a population-based community cohort of patients with advanced non-small cell lung cancer.*

[3] Lamba, N., et al. (2020). *Disparities in microsatellite instability/mismatch repair biomarker testing for patients with advanced colorectal cancer.*

[4] Lewis, M.A., et al. (2021). *Biomarker testing in patients (pts) with metastatic colorectal cancer (mCRC): Survey of U.S. oncologists (ONC) in rural areas and urban clusters.*

Understanding Provider Utilization of Cancer Biomarker Testing

- ACS CAN conducted a survey of 315 oncology providers examining barriers providers face in performing recommended cancer biomarker testing
 - Patient concerns about cost and coverage are seen as key barriers
 - **Two-thirds** report that patient insurer coverage for a desired biomarker test is a significant or moderate barrier.
 - Insurance obstacles are the most frequently mentioned concern in an open-ended question
 - Enacting better coverage policies is seen as one of the most important ways to improve providers' ability to test patients for biomarkers
 - **Nearly nine-in-ten** providers agree that biomarker testing can help them to make more informed treatment recommendations
 - **91%** consulted clinical guidelines in deciding to test



Legislation to Address Coverage

- Requires *state-regulated insurance plans including Medicaid* to cover comprehensive biomarker testing when supported by medical and scientific evidence*
- Disease and stage agnostic

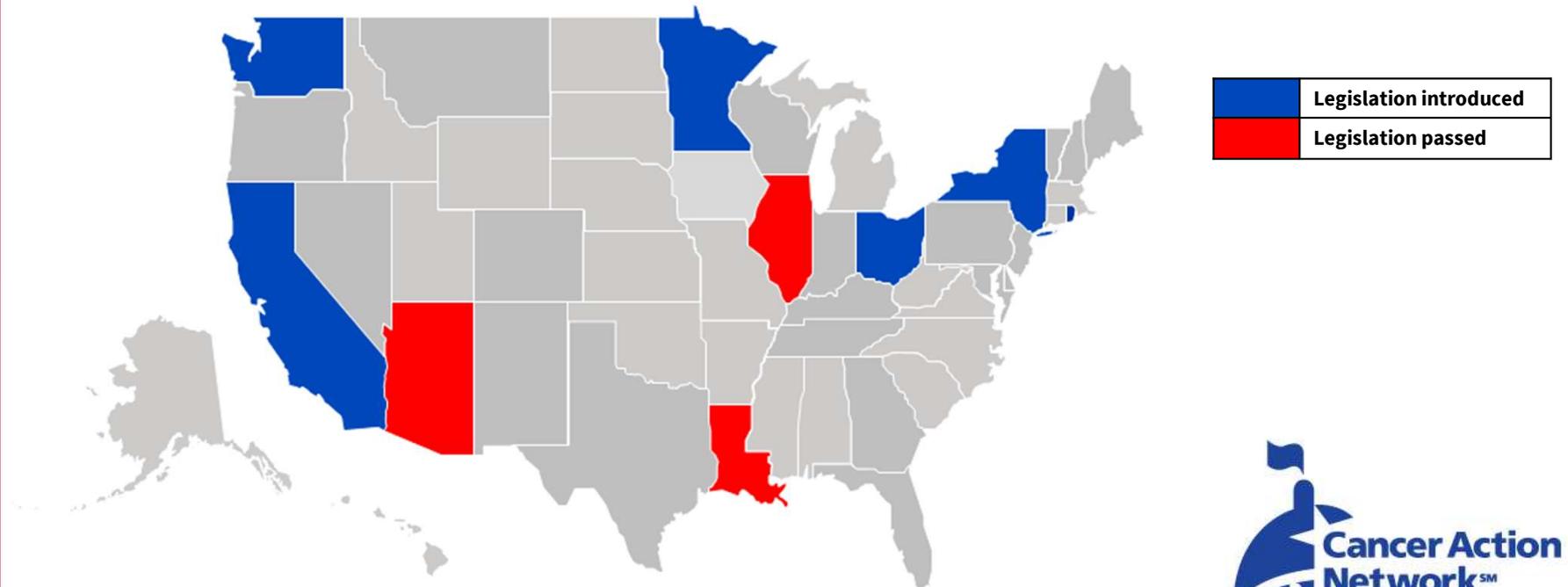


Legislation to Address Coverage

Biomarker testing must be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition when the test is supported by medical and scientific evidence, including, but not limited to:

- 1. Labeled indications for an FDA-approved or -cleared test or indicated tests for an FDA-approved drug;*
- 2. Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations and Medicare Administrative Contractor (MAC) Local Coverage Determinations; or*
- 3. Nationally recognized clinical practice guidelines and consensus statements.*

Legislation to Expand Access to Biomarker Testing



Legislation introduced (2022): CA, MN, NY, OH, RI, WA

Legislation passed: AZ (2022), IL, LA (2021)





Ruth's Biomarker Story



I remember when my husband and I were young,
we had a lot of fun together. It was just the way

fightcancer.org/biomarkers

