

# Biomarker Testing and Precision Medicine

# Michael's Story



# What are biomarkers?

**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. Includes *gene mutations* or *protein expression*.

## The right treatment at the right time

- An essential component of precision medicine
- Targeted cancer therapy
- Avoidance of therapies unlikely to provide clinical benefit

## Not just about cancer:

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



# Screening vs. Genetic testing vs. Biomarker testing

## Screening tests – like MCED, mammograms, PSA testing

Looking for signs of cancer in general population

## Genetic testing

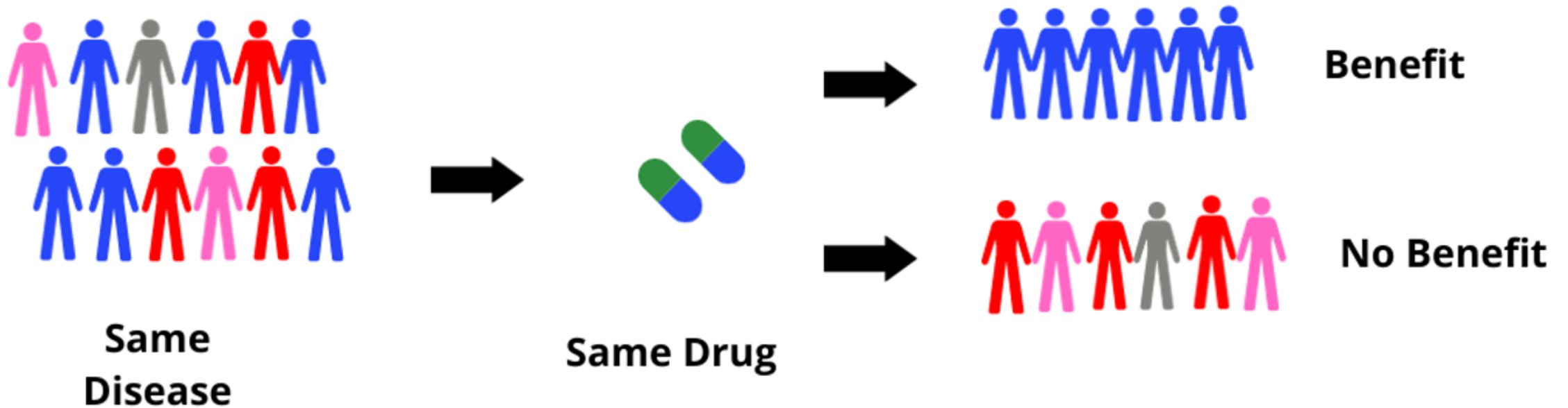
Testing for inherited risk to determine risk for developing certain cancers or passing risk onto children

## Biomarker testing

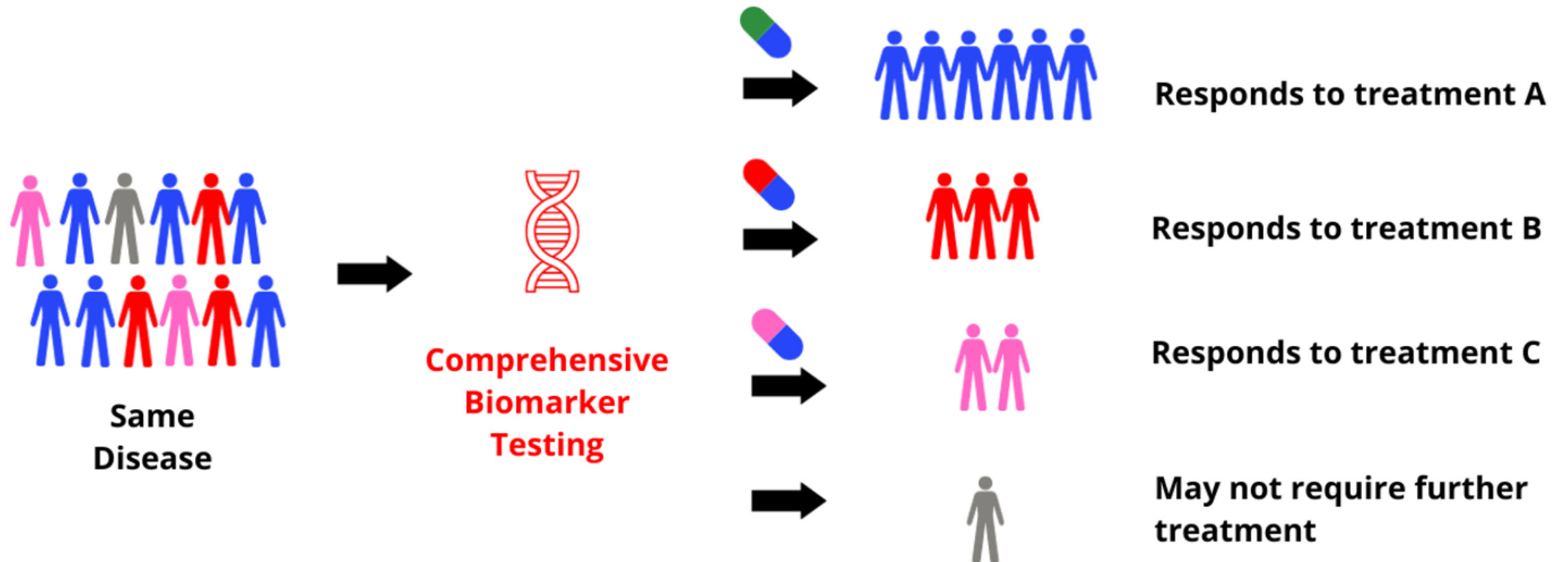
Used in people who already have cancer (or another condition) to determine best treatment options, how aggressive the disease is, monitor for recurrence



# Conventional Approach – Trial and Error



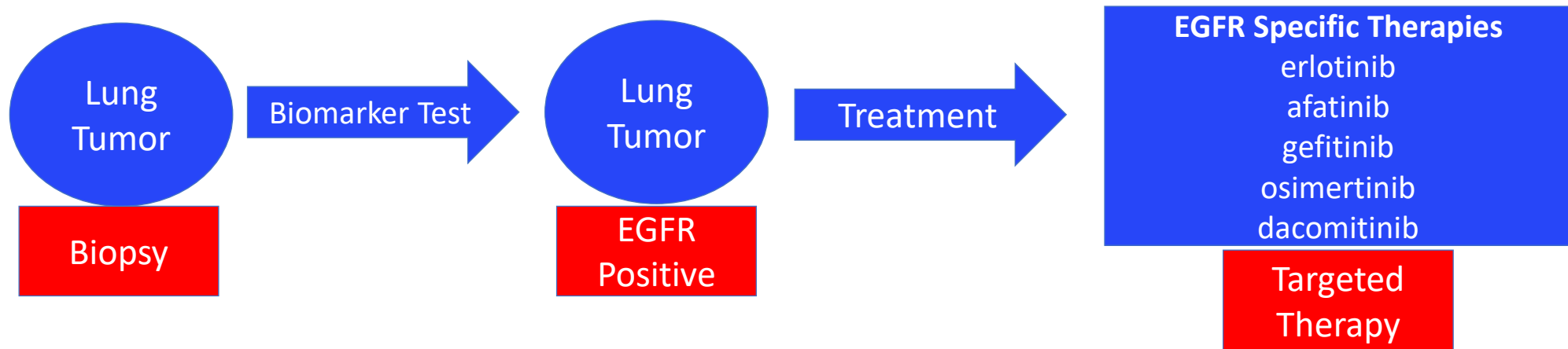
# Precision Medicine with Biomarker-Informed Treatment Selection



# 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 and treatment decisions
- Example: EGFR-positive non-small cell lung cancer --> several EGFR inhibitors



# 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
- Helps 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.**





# Who is getting tested?

## Unequal access to testing

- In metastatic non-small cell lung cancer (NSCLC), **eligible Black patients are less likely to receive biomarker testing** compared to white patients.
- Patients with advanced NSCLC or colorectal cancer who were **Black, older, or Medicaid-insured** had **lower odds of next-generation sequencing biomarker testing** compared to patients who were white, younger, or commercially insured.
- There are **socioeconomic inequalities** in biomarker testing and targeted therapy utilization across cancer types.
- There **are lower rates of testing in community oncology settings versus academic medical centers**.

**These disparities in access and use of guideline-indicated biomarker testing and targeted therapy can potentially widen existing disparities in cancer survival.**



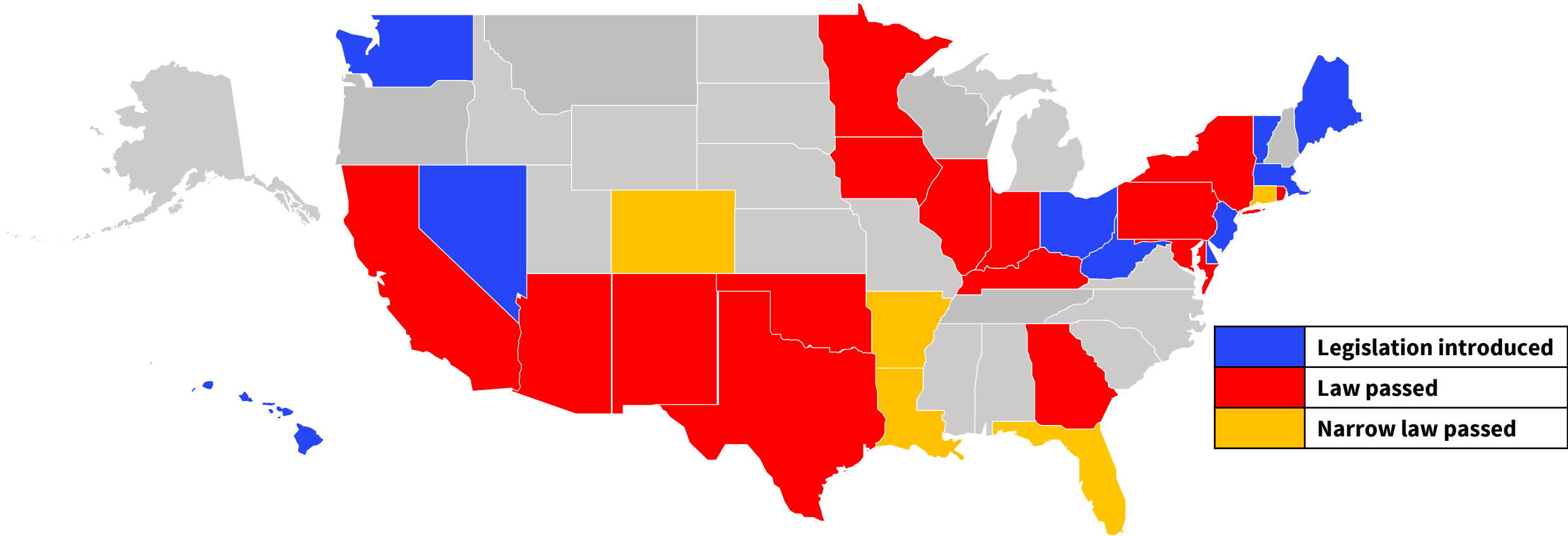
# Legislation to Address Coverage Gaps

**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 Expand Access to Biomarker Testing



Legislation enacted: AZ, AR\*, CA, CO\*, CT\*\*, FL\*\*, GA, IL, IN, IA, KY, LA\*, MD, MN, NM, NY, OK, PA, RI, TX

Legislation introduced: HI, MA, ME, NV, NJ, OH, VT, WA, WV

\* Private plans only      \*\*Public plans only

Updated 7/2/2024

# Broad Patient & Provider Support for Biomarker Testing



# Key Takeaways

- **Personalized treatments are helping cancer patients live longer and better.**
- **Biomarker testing helps connect patients with the most effective treatment for their cancer and avoid treatments that will be ineffective.**
- **Without action to improve access to biomarker testing, some patients are left behind from the latest advances in cancer treatment.**
- **Patient stories are SO powerful!**



**Learn more:**

**[fightcancer.org/biomarkers](https://fightcancer.org/biomarkers)**

# Questions?