Maximizing RWD Insights in Precision Medicine for Patients with Cancer

STAT in MED
The Authority in RWE

When it comes to precision medicine, advances in technologies and treatments have provided near cures for patients with previously incurable cancer, and several more options for those with genetic and immune conditions. Recognized for over a decade, testing of tumors has clinical validity and utility and principles of biomarker testing are incorporated in clinical practice guidelines, including:

- **National Comprehensive Cancer Network**
- **(NCCN) American Society of Clinical Oncology**
- **(ASCO) American College of Surgeons (ACS)**
- **College of American Pathologists (CAP)**

Real-world data (RWD) reflects an evolution in clinical practice patterns. This monitored evolution is generally from academic centers that first gain experience and refine the diagnostic and therapeutic approach to a few highly-resourced large clinical centers, followed by more widespread adoption. While gradually expanding, access to care is also influenced by patient resources and logistics.

Current Disparities and Challenges

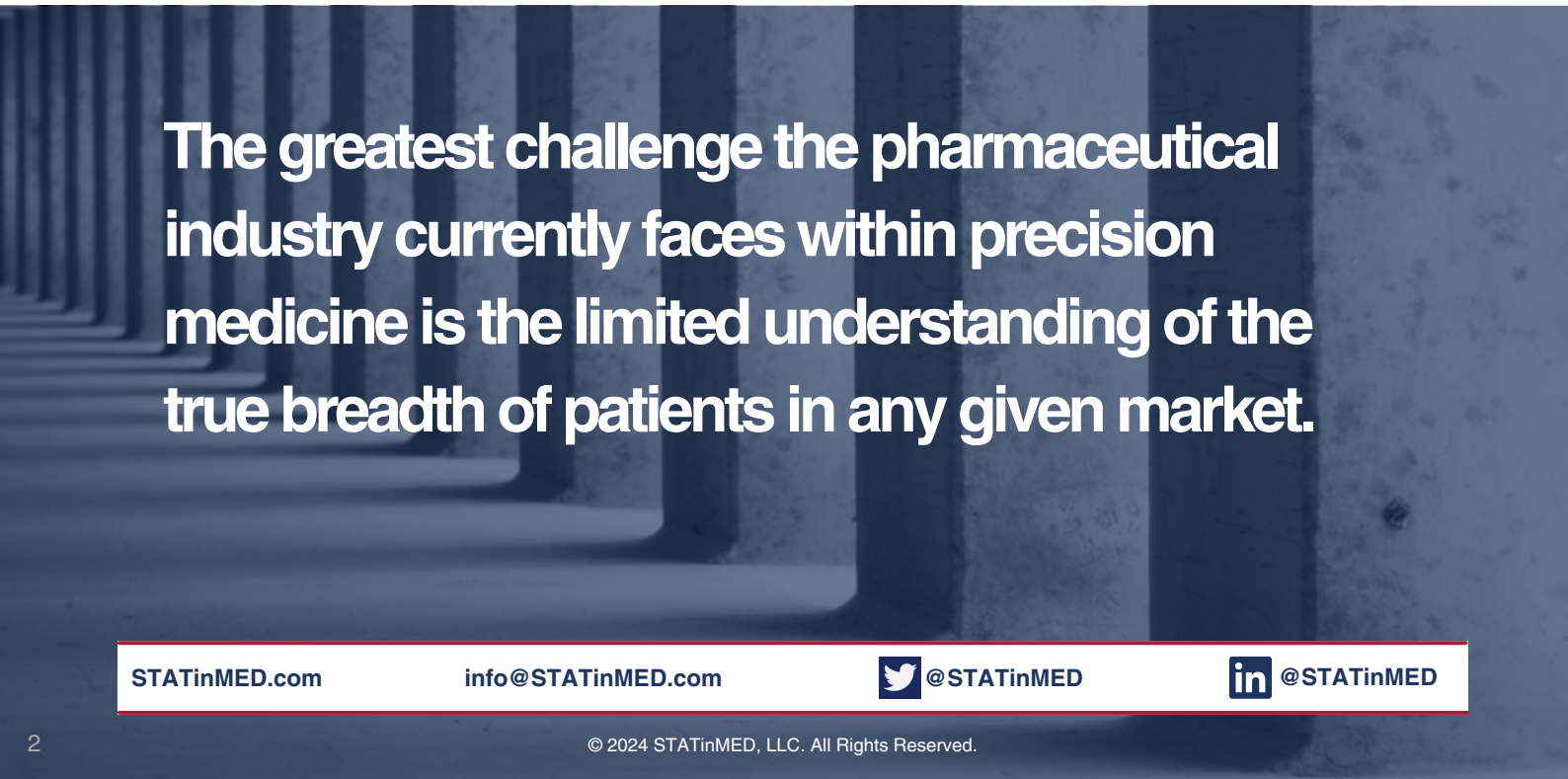
Disparities exist in clinical care practices across the country, where patients may receive treatment but do not receive key biomarker genetic testing.

Smaller community-based and regional practices often do not send patients for tests due to cost or lack of insurance coverage, despite recommendation by the provider.

As seen with the implementation of genomic testing for prostate cancer, challenges exist based on regional healthcare and patient resources. Rapid regional adoption of genomic testing was associated with higher measures of income, education, and prostate cancer services.

Based on findings from the 2020 World Conference on Lung Cancer, fewer than half of community oncologists use biomarker testing to guide treatment discussions with patients, compared with 73% of academic clinicians. The latest advances in cancer genomics and targeted therapies may not be equitable throughout the health care system, further reinforcing disparities for patients in underserved populations.

In addition, current policies for some of the top insurers in this country may deem key genomics tests as experimental and not medically necessary.



Value of Testing

Taking a step back, despite vast clinical literature and studies that demonstrate success of precision treatments for various conditions, there is a lack of real-world evidence (RWE) supporting the value of testing.

Without readily-available testing for patients, the pharmaceutical industry is limited to the potential positive population of the total patient population tested.

With STATinMED RWD Insights we have the power to examine more than 80% of the US healthcare system's all-payer medical and pharmacy claims, with patient- level data across all-provider types to support a variety of evidence generation needs.

Specifically, in an analysis of approximately 750,000 patients with breast cancer captured in RWD Insights powered by STATinMED who received care in 2020, we found that only 22% had a BRCA genomics test, and research-available BRCA results represented less than 1% of the broader patient population. This is an extremely important revelation to consider in the fragmented data landscape.

Limitations

Generating RWE within the precision medicine space is possible but limited due to the lack of available genomics data for research purposes. While all-payer medical and pharmacy claims information in the United States is robust with real-world data readily available, genomics data is hard to come by with just a handful of laboratories to run tests.

Sample sizes are also extremely limited. If we were to look for a particular genomics test and patients taking a specific product, samples sizes drop drastically, making it difficult to achieve statistically significant results.

The cost of data is extremely high with the range of $600,000 to $750,000 for a single study of less than 1000 patients with a genetic test. This does not include patients positive for a particular genomics marker.

Recommendations to Maximize Evidence Generation Approach

We strongly recommend an RWE generation approach focused on:

- **Demonstrating the value of testing**
- **Reducing the cost of care**
- **Improving patient outcomes**

> Conducting these types of studies supports communication with payers, with the hope that evidence drives genomics testing to be more readily available to patients, taking it from “experimental” consideration to mandatory input for a particular patient population.

The Authority in RWE

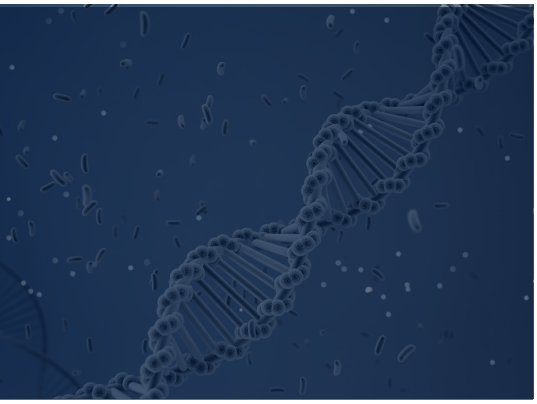
Industry partners for 14+ years
Hundreds of combined experience years
1000+ peer-reviewed publications

STATinMED uses the best RWD to generate RWE that answers research questions and solves problems with confidence.

Need more evidence? Email us to learn more.

Considerations

STATinMED
The Authority in Real-World Evidence



Genomics data on patient biomarker status is costly and limited, providing few additional details on patient treatment, disease history, etc. to support analysis on its own. **When partnered with STATinMED's robust claims data RWD Insights, we maximize deeper analysis about the patient experience and payer details.**

Utilizing less restrictive criteria in the study design can provide broader sample sizes while maintaining clinical accuracy. **Conduct studies focused on patient populations with specific diagnoses or conditions, and different segments across all 50 states with Medicaid, Medicare FFS, or Medicare Advantage coverage.**

Consider collaboration with patient advocacy groups to offer free testing that in turn increases the addressable market and data availability.

Let's talk!

Jason Drenning, PhD
Chief Commercial Officer
jdrenning@statinmed.com

Keshia Maughn, MPH
Sr. Principal, Strategic Advisory Services
kmaughn@statinmed.com

Sources

Engstrom PF, Bloom MG, Demetri GD, et al. NCCN Molecular testing white paper: Effectiveness, efficiency, and reimbursement. JNCCN. 2011;9(Suppl 6):S1-S16.

Febbo PG, Ladanyi M, Aldape KD, et al. NCCN Task Force Report: Evaluating the clinical utility of tumor markers in oncology. JNCCN. 2011;9(Suppl 5):S1-S31.

Leapman MS, Wang R, Ma S, et al. Regional adoption of commercial gene expression testing for prostate cancer. JAMA Oncol. 2021;7:52-58.

RWE Insights. STATinMED.