NEO GENOMICS

ONCOLOGY DATA SOLUTIONS

WHITE PAPER

Bridging HER2 Testing and Treatment: Closing the Gap Between Diagnosis and HER2-Targeted Therapy Across 22 Solid Tumors

Real-World Evidence from 18,844 Patients
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HER2 (human epidermal growth factor receptor 2) is a well-established oncology biomarker and the target of a growing class of approved therapies. Yet, across more than 18,000 real-world patients, only half of HER2-positive patients actually received HER2-targeted treatment.

This analysis presents findings from large-scale, real-world data examining HER2 testing patterns, positivity rates, and prescribing behavior across 22 solid tumor types, with a focus on the community oncology setting, where most cancer patients receive care.

The opportunity: HER2 beyond breast cancer

For decades, HER2 testing was largely associated with breast and gastric cancer. That has changed significantly in recent years. Approved indications now span colorectal, lung, endometrial, cervical, and biliary cancers, among others, and the pipeline continues to grow.

Despite expanded approvals and a sharp rise in testing volume, this analysis reveals a persistent gap: many HER2-positive patients are not being matched to the therapies designed for their biology. Understanding where, why, and in which tumor types this gap is widest is essential for improving outcomes.

Key numbers at a glance

18,844 Patients analyzed

4.5x Increase in HER2 testing over 10 years

56% HER2+ patients receiving targeted therapy

Study overview

This analysis integrated two complementary data sources to build a comprehensive picture of HER2 testing and treatment in the real world:

- 10 years of HER2 testing data from NeoGenomics, including a focused cohort of 18,844 patients tested between December 2023 and December 2025.
- Clinical records aggregated via a national health information exchange (HIE) and processed through the xCures platform, which used large language model (LLM)-based natural language processing to extract structured data from pathology reports, physician notes, prescriptions, and imaging records.

The study population reflects where most cancer patients are treated: over 80% were seen in community oncology settings rather than academic medical centers. This makes the findings particularly relevant for everyday clinical practice.

HER2 testing grew more than 17% year-over-year from 2023 to 2025, a clear sign that oncologists/pathologists are expanding their biomarker workup in certain tumor types. The challenge now is ensuring test results translate into treatments.

Key findings

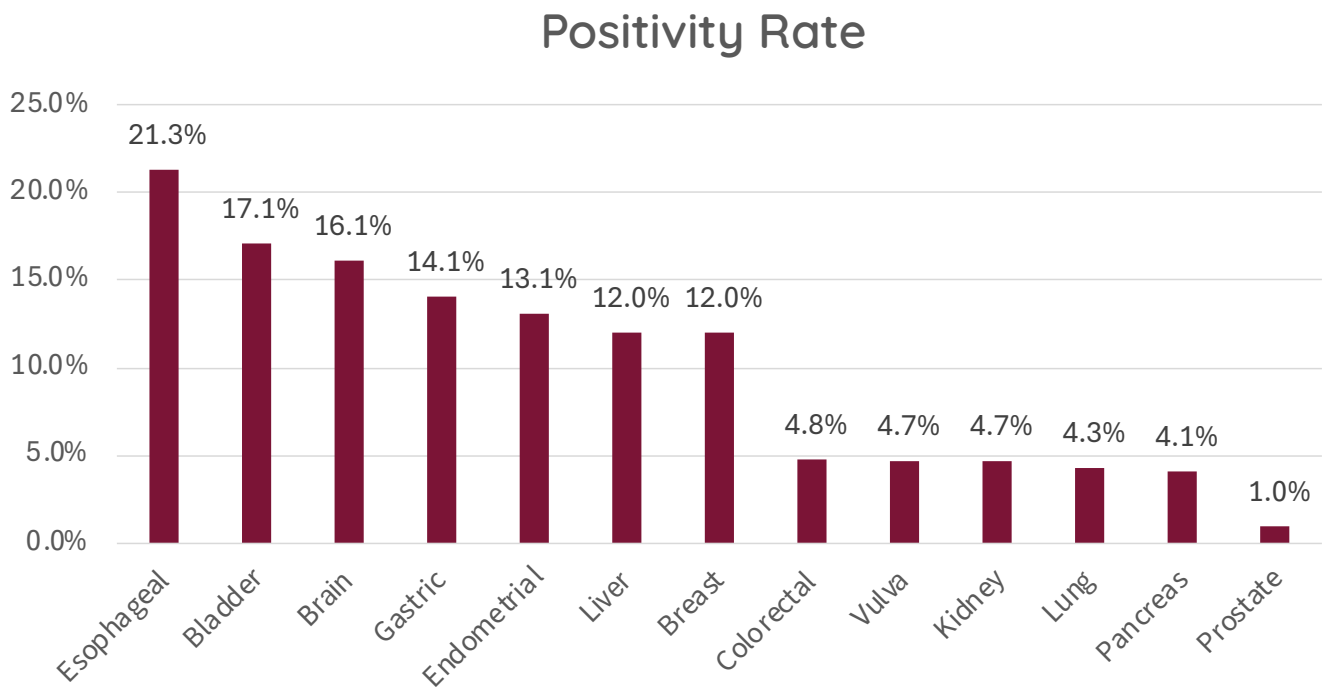
HER2 testing is rising—rapidly

Over the past decade, HER2 testing volume increased 4.5-fold. In just the 2023-2025 window, testing grew more than 17% year over year. The most commonly tested tumor types were breast, lung, colorectal, gastric, and endometrial cancers, collectively accounting for 89% of all HER2 testing.

HER2 positivity varies widely by tumor type

HER2 positivity (defined as IHC 3+ or FISH amplification) ranged from over 21% in esophageal cancer to just 1% in prostate cancer.

HER2 positivity rates by tumor type (IHC 3+ or FISH amplification)



Treatment utilization falls short

Among patients with treatment information available within 90 days of HER2 testing, only 56% of HER2-positive patients received any HER2-targeted therapy.

HER2-targeted therapy utilization (n=573)	
Received HER2-targeted therapy	56%
Did not receive HER2-targeted	44%

Breakdown of HER2-targeted regimens used

Pertuzumab + trastuzumab	52.0%
Trastuzumab (monotherapy)	25.0%
Trastuzumab deruxtecan (T-DXd)	6.3%
Pertuzumab (monotherapy)	5.4%
Trastuzumab emtansine (T-DM1)	3.1%
Pertuzumab + trastuzumab + T-DM1	1.8%
Other combination therapies	1.8%
ERBB2 TKIs	1.3%

44% of HER2-positive patients did not receive HER2- targeted therapy within 90 days of testing. Newer HER2-directed agents were used in a small percentage of patients, with trastuzumab deruxtecan accounting for fewer than 7% of those treated.

Notably, newer-generation HER2-directed agents—particularly antibody drug conjugates (ADCs) like trastuzumab deruxtecan—were used in a small minority of patients, despite growing clinical evidence supporting their efficacy across tumor histologies.

Implications for oncology practice

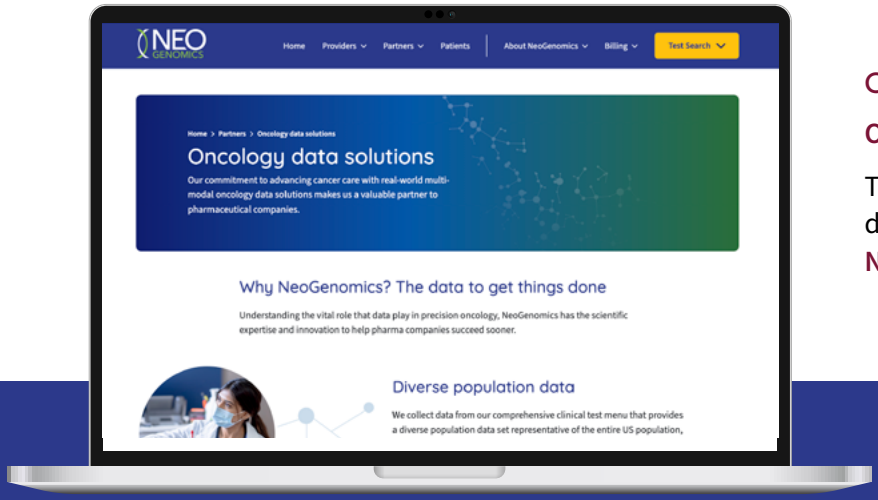
These findings point to several actionable opportunities for the oncology community:

- Expand reflexive HER2 testing to tumor types with meaningful positivity rates (e.g., esophageal, bladder, endometrial). Many still lack standardized testing protocols outside of breast and gastric.
- Ensure treatment decisions reflect current evidence. Newer HER2-directed therapies, including pan-tumor ADCs, have demonstrated activity beyond traditional HER2-positive cancers.
- Leverage technology to close the loop. LLM-based clinical data extraction—as used in this study—can help identify HER2-positive patients who may not yet be receiving matched therapy.
- Address the community-setting gap. The vast majority of patients in this study were treated outside academic centers. Targeted education, care management support, and streamlined testing pathways are needed in community oncology.

Conclusion

This analysis documents a substantial increase in HER2 testing across solid tumors alongside a persistent gap between testing and treatment: more than 40% of HER2-positive patients did not receive a HER2-targeted therapy within 90 days of testing, and newer-generation agents accounted for a small share of the regimens used. The size of this gap varied by tumor type and was most apparent in community oncology settings, where the majority of patients in this study received care.

With new approvals expanding HER2 treatment options across all solid tumor types, understanding trends in the testing landscape is paramount to driving clinical research direction and optimizing treatment paradigms for all patients, with particular emphasis in the community setting. As the HER2 space continues to evolve, insights from the NeoNucleus™ database will continue to provide crucial understanding to all relevant stakeholders across the drug development and commercialization lifecycle.



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Oncology diagnostics is a vast, fluid, and ever-changing landscape. The testing, real-world data, and world-class expertise of our Oncology Data Solutions evolve as guidelines and clinical practice evolve. Improving patient care means capturing the complete picture of a patient population, and with >85% of testing coming from the community setting, we are uniquely positioned to explore changes in testing trends and real-world biomarker prevalence in the U.S. Connect with our Biopharma data team to discuss how we can support your development and commercialization efforts with our NeoNucleus™ database in a rapidly evolving oncology landscape. Through linkage with claims and integration with third-party data, we can glean further insights across the patient journey from initial diagnosis to treatment selection and response.

Connect with our team: OncologyDataSolutions@NeoGenomics.com

About this research: Data was sourced from the NeoGenomics molecular testing database and clinical records aggregated from a national health information exchange, and processed via the xCures platform. Findings were presented at ISPOR 2026. This white paper summarizes findings from the published abstract.

NeoGenomics, Inc. is a premier cancer diagnostics company specializing in cancer genetics testing and information services. We offer one of the most comprehensive oncology-focused testing menus across the cancer continuum, serving oncologists, pathologists, hospital systems, academic centers, and pharmaceutical firms with innovative diagnostic and predictive testing to deliver timely, actionable insights that guide personalized care decisions. Headquartered in Fort Myers, FL, NeoGenomics operates a network of CAP-accredited and CLIA-certified laboratories for full-service sample processing and analysis services throughout the US and a CAP-accredited full-service sample-processing laboratory in Cambridge, England.

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