TEMPUS | APPS

CASE STUDY

An algorithmic approach to close care gaps for patients that may benefit from confirmatory IHC HER2 testing

In partnership with a global pharmaceutical company, Tempus Next deployed a HER2 predictive algorithm at selected sites within the Tempus network. This algorithm was used during routine xR (whole transcriptome RNA) tests to identify patients who may benefit from additional confirmatory IHC HER2 testing.

EXECUTIVE SUMMARY

- **74 accounts** across the Tempus network representing **5,095 MDs**, have opted into the Tempus Next HER2 program during the first 3 months of deployment from July through October 2024.
- **10,104 patients** were screened across **9 cancer types**.
- **550 patients** were identified as potentially HER2 positive and their providers were notified to consider follow up IHC testing.

THE CHALLENGE

The last decade has seen a surge in the approval of precision therapies, which has led to increasingly intricate and frequently revised clinical guidelines. This complexity has contributed to ongoing care gaps and has hindered the widespread implementation of precision medicine. Furthermore, essential clinical details are often hidden within unstructured patient data across different systems, making it challenging for healthcare providers to determine which patients might qualify for precision treatment options.

Consider the case of human epidermal growth factor receptor 2 (HER2); HER2 is a well-established therapeutic target in patients with breast or gastric cancer determined by HER2 overexpression in IHC or FISH testing.[1] In recent years, the indications for HER2-targeted therapy have expanded beyond these tumor types to include various other HER2 overexpressing solid tumors.[2] Given the recent changes in NCCN and other care pathway guidelines, HER2 testing is not always done in this expanded population, which may lead to not identifying patients who qualify for a targeted therapy option based on guidelines.

A global pharmaceutical company, was seeking to understand the effectiveness of Tempus's care gap algorithm in identifying patients who may not be receiving guideline-based HER2 testing, and gather insights to understand whether patient identification and provider education can close that care gap.

THE SOLUTION

Tempus Next is designed to identify care gaps and equip clinicians with actionable insights at the point of care. Tempus Next HER2 surfaces patients who are more likely to test positive for actionable biomarkers like HER2, and who should receive confirmatory testing in accordance with clinical guidelines. A global pharmaceutical company partnered with Tempus on this initiative to gather data and identify insights associated with care gaps related to HER2 IHC testing, which is recommended under clinical guidelines in multiple metastatic tumor types.[3]

The HER2 algorithm, which is run as part of Tempus' xR Laboratory Developed Test in routine clinical care, uses RNA data to predict IHC/ISH positivity in a tumor sample in order to identify patients who may benefit from confirmatory IHC HER2 testing.[4] Orders for the Tempus xR RNA panel, from participating sites that meet patient cohort criteria, are flagged for RNA overexpression analysis. Tempus developed the algorithm with a targeted PPV of 80%, meaning that it designed the algorithm with the goal that, on average, 80% of patients with a positive test result would be expected to be HER2 positive.[5]

THE RESULTS

74 accounts across the Tempus network, representing 5,095 MDs, opted into use of the Tempus Next HER2 screening algorithm during the first 3 months of deployment from July through October 2024. Tempus notified physicians of patients who were identified by the algorithm as more likely to be HER2 positive, so that they could consider ordering confirmatory IHC testing from their laboratory of choice. 550 patients were identified as potentially HER2+ and their providers were notified to consider follow-up IHC testing.[6]

As part of our measurement to assess the effectiveness of the program, Tempus generates periodic data reports with insights consisting of metrics and data visualizations for the patients

identified by the care gap algorithm and (if available) the aggregated known IHC test results for these patients, along with the geographic representation of where IHC testing occurred. These data views give visibility into the patient staging and rates of provider participation in the program across the US. This data will be instrumental for partners as they start to better understand the HER2 landscape across tumor types.

Tempus Next HER2 program identified 550 patients as potentially HER2+ and surfaced for follow up IHC testing

JULY–OCTOBER 2024

Sites opted into algorithmic screening for possible HER2 positivity[6]	74
Clinicians participating in the Next HER2 Screening network	5,095
Patients screened across 9 cancer types*	10,104
Patients identified as potentially HER2+	550

**Bladder, BTC, Cervical, CRC, Endometrial, NSCLC, Ovarian, Pancreatic, and Salivary Gland cancer*

THE IMPACT

Post-deployment we are monitoring and evaluating the impact that Tempus Next can have on HER2 testing awareness and guideline directed IHC testing through its broader educational effect. Programs like Tempus Next have the potential to identify patients who may be particularly likely to benefit from precision care and effect change in precision care delivery at scale. Ultimately, accelerating physician adherence to clinical guidelines helps improve care for all cancer patients, given the significant benefits to patient outcomes from targeted therapy.

HEAR FROM A PARTNER SITE

The Tempus HER2 predictive algo helps our team avoid care gaps related to HER2 IHC testing and helps our clinicians know about potential treatment options even before the patient needs them. This allows our team to be proactive about patient care rather than scrambling to order HER2 testing at time of progression.

/// Dr. Ryan Nguyen, Medical Oncologist and Head of Precision Oncology Tumor Board, University of Illinois Chicago

Broader geographic reach is possible with Tempus Next: feasibility assessment

Through a retrospective feasibility assessment, Tempus assessed the potential sites in our network that could benefit from opting into the Next HER2 program in future deployments. Tempus found the highest predicted HER2+ patients in Bladder (563), NSCLC (453), and Colorectal cancer (253), with significant counts in Endometrial (134), Ovarian (97), BTC (96), and Pancreatic (76) as well.

In an analysis across 49 states and Puerto Rico, the South, and Midwest regions emerged with the highest counts of predicted positive patients, tallying 571 and 566 respectively. In contrast, the West and Northeast regions reported a lower number of identified patients, with totals of 300 and 108 respectively. This analysis supports the significant potential impact of this care gap intervention.

1 *Yoon, J., Oh, DY. HER2-targeted therapies beyond breast cancer — an update. Nat Rev Clin Oncol 21, 675–700 (2024). https://doi.org/10.1038/s41571-024-00924-9*
2 *FDA grants accelerated approval to fam-trastuzumab deruxtecan-nxki for unresectable or metastatic HER2-positive solid tumors*
3 *The development of this program was funded by Tempus and one or more life sciences company sponsors*
4 *Results from the algorithm should not be used as evidence of HER2 status or be used to inform treatment decisions*
5 *Internal analysis*
6 *Data on file from internal analysis*

Contact us to learn more

next-id@tempus.com