



# DIAGNOSTIC TESTING & Emerging Technologies

## Companion Diagnostics Driving New Model for Pharma-Dx Partnerships

**W**ith a growing number of approvals for companion diagnostics, the pharmaceutical industry is taking keen interest in testing uptake and thinking about steps it can take to further drive testing.

A white paper by pharmaceutical advisor Diaceutics (Ireland) shows that a sizable percentage of U.S. oncology patients are missing out on targeted therapies due to a combination of testing “quality gaps” (e.g., turnaround time, test sensitivity, and sample management issues) and slow test diffusion. While this “lag” in testing adoption (driven by lack of physician awareness, reimbursement issues, and lack of inclusion in clinical guidelines) slows therapy demand (a concern for pharmaceutical companies), Diaceutics says it also prevents patients from receiving optimal therapy.

Diaceutics used real-world data from U.S. labs and claims databases to assess the patient and pharmaceutical financial impact resulting from nonideal integration of testing into the therapeutic business model. The assessment included only actual testing issues based on data for 13 oncology biomarkers (HER2, PD-L1, VEGF, EGFR, MET, ALK, BRAF, BRCA, RAS, KRAS, IDH2, FLT3, JAK2) and did not include quantification of the number of patients who should or could be tested if there were faster test adoption at the physician and laboratory levels.

Peter Keeling, Diaceutics’ CEO, reports that there is a “significant lost targeted treatment opportunity” estimated to be about 6,500

oncology patients per month or 78,000 patients per year in the United States alone. These patients did not receive targeted treatment because the test results were incorrect, too late, or inconclusive due to sample issues. The actual number of patients not receiving therapy because of slow test adoption is likely much higher.

“In the real world clinical setting, achieving this synchronization of test and therapy is proving extremely difficult,” Keeling says. He adds that testing and therapeutic adoption both will be enhanced when the diagnostics and pharmaceutical industries stop viewing these as two separate, parallel technologies, but rather as a single, integrated solution.

## The Economics of Companion Diagnostics

Diaceutics previously estimated that for every dollar invested in diagnostics, the pharmaceutical industry could expect between \$30 and \$60 back in additional therapy revenue. Combining this estimate, with the recent findings that 30 percent to 50 percent of patients are not receiving targeted therapy due to testing issues and/or slow test uptake, Diaceutics suggests that further investment in test adoption could yield “rapid” returns through an increased share of patients receiving testing and, ultimately, the therapeutic product.

“Most of the top 10 pharma companies have a recognizable center of diagnostic planning and have awoken to the fact that their technology-centric diagnostic partners—whilst supporting their test development and regulatory goals—are ill-equipped to support the all-important clinical diffusion and laboratory adoption goals,” Keeling writes in the white paper. “As a result, these therapy teams are having to learn how the diagnostic market can support their assets and fill the gaps in development infrastructure created by an underfunded diagnostic industry.”

Keeling explains that pharmaceutical-diagnostic partnerships are typically split into two phases—the development portion, which is usually a fee-for-service payment to the diagnostics company, and a commercial agreement, often developed later in the process along with launch plans. The development payment, which can range from \$5 million to \$25 million per biomarker, is a “small” investment accounting for approximately six percent of the total spend for commercializing a therapeutic.

“We think this model is flawed since it leaves planning the critical commercial architecture much too late to stay in step with the needs of the therapy launch,” Keeling says. He tells *DTET* that Diaceutics argues for “considerably more openness about the commercial bandwidth of diagnostic companies so the total partnership can then focus on what the gaps are and invest in those. Our experience is that our pharma clients are wakening to these commercial limitations and limiting the role of their diagnostic companies to what their known strengths are.”

Given that launching diagnostics in tandem with therapeutics is more complex than launching either as a standalone, Keeling sees the evolution of a new type of partnership emerging that eliminates the learning curve for each launch and focusses on filling in the gaps associated with these dual launches. He sees companies like Diaceutics playing a future role in aligning testing and treatment commercialization.

*Takeaway: Pharmaceutical-diagnostic partnerships are evolving to more fully align testing adoption and treatment commercialization to realize both maximal patient benefit and full return on investment.* 