THE DIAGNOSTIC REIMBURSEMENT SYSTEM IS NOT BROKEN

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Don't Assume the Diagnostics Reimbursement System is the Problem

"Biotech has been an attractive sector for investors over the past few years, but omics and molecular diagnostics companies have encountered regulatory uncertainty and reimbursement headwinds that have led some investors to divert capital to more certain sources of return."
– GenomeWeb, August 16th, 2016

(Regulatory Uncertainty, Reimbursement Challenges Seen Harming Investments in LDT Developers, 2016)

For ten years or more, it's been a cliché across the diagnostics industry that "the reimbursement system is broken." We argue that this is a self-defeating myth that prevents diagnostics innovators from creating solutions that will succeed. Innovative ventures, in medicine as elsewhere, always face high uncertainty, including technical risk (that the science will come up short) or business risk (that competitors will out-maneuver you). Successful entrepreneurs and innovators see these issues as challenges, not as barriers.

The real hallmark of a market failure is not when products fizzle, but when they aren't brought to market at all. For example, in today's market, it would be overly onerous for a diagnostic company, without pharma assistance, to invest in costly long term clinical trials to demonstrate when a drug does or does not work and show whether prescriptions are required or should be reduced.

Our point is that most failures in diagnostics are either (1) the clinical impact is not strong enough (meaning that the unmet need is not actually being met), or alternatively, (2) that the clinical impact is probably there, but it remains unproven to clinicians, regulators, or payers. Yet diagnostics developers who come up short in proving these points often point to the reimbursement system as inherently flawed, without understanding the real dynamics of what has happened.

The diagnostics industry has enormous potential to positively impact the future of healthcare, both in terms of quality and costs. But to do so, it needs to focus on securing the investment to support development of clinical utility evidence and articulate the proximate ROI. There is no other pathway. If the use case is accurate, and there is a real unmet clinical need, then an evidence-based approach will help assure both skeptics and policymakers that a diagnostic technology can provide the right solution.

Setting Appropriate Expectations

Clinical utility is not a foreign concept to all of us operating in the reimbursement world. However, this is a nuanced topic that often evades investors, and many times, the proverbial C-Suite, particularly when their experiences stem from the pharma where FDA approval almost guarantees some level of market access. But if investor and C-Suite unfamiliarity are the problem, it's hardly a market failure. It's a difficulty in understanding the real-world environment that the business leaders must navigate when bringing diagnostics to market.

In the tech and innovation world, most internal and external pressures focus on timeline to product launch. In the drug world, that inherently includes FDA approval which in turns nearly guarantees a shot on goal in the marketplace. But in the diagnostics field, the key milestones must follow a story arc that includes adoption and revenue. Those two factors mean first that clinicians are bought in to your diagnostic, and second, that payers are supporting its use.

As such, it is important to clearly see that the market situation is counter to that in biopharma. In the biopharma world, time to market is almost always one of the greatest hurdles, and even more so as patent periods

dwindle. But for diagnostics, time to market has rarely been a challenge. Simply show your test is reproducible and accurate, seek CLIA-approval, and then power-up your sales force to meet speculative and often naïve revenue expectations[1]. This is the mentality that has inefficiently burned so much capital and ultimately limited, rather than facilitated, the commercial ramp for many diagnostics. In the absence of coverage even a great sales force can't save your product. Industry leaders need to educate themselves and the investor community that resource allocation in payer-centric evidence will provide fruitful returns.

Evidence Is Not Optional, But It Is Dynamic

Payer medical policy is clear: coverage is contingent on peer-reviewed published evidence of clinical utility. There are many checklists and frameworks that help innovators understand what clinical utility means. Blue Cross Blue Shield have long had five criteria that must be satisfied for a successful technology assessment. (Assays of Genetic Expression in Tumor Tissue to Determine Prognosis in Breast Cancer Patients, 2016)

- The technology must have final approval from the appropriate government regulatory bodies
- The scientific evidence must permit conclusions concerning the effect on health outcomes
- The technology must improve the net health outcome
- The technology must be as effective as any established alternatives
- The improvement must be attainable outside the investigational settings

These requirements provide a skeleton of issues to address, but don't provide a roadmap for any particular product. Creating that roadmap is a dynamic exercise that must incorporate multiple inputs:

- What is the Unmet Need Associated with Standard of Care?
- How Will Physicians Behave Differently?
- Will Comparative Patient Outcomes Improve?
- What Is the Economic Impact to Health Plans?

10 years ago, the minimum entry data set was that manufacturers could validate their test (e.g. marker X correlates with Y), leverage retrospective data sets, and conduct vignette-based physician surveys to satisfy payers. Over the last 5 years, payer standards have clearly become higher. Today, manufacturers have had to invest in prospective data, even if observational in nature, to develop at a minimum a "chain of indirect evidence" to support utility and coverage.

If you look at the current payer environment objectively, there's an increasing need to show actual real-world comparative data to understand a relative change in behavior and in outcomes driven by the test. The need for rigorous evidence is not a trend, not a short-term shift in market dynamics, it's a requirement. We firmly believe that the equation to find investable and clinically feasible evidence plans is a solvable one, but it takes discipline and commitment. Good investors and innovators will be able to clearly ask and define questions like these:

- What clinical population and scenario is the diagnostic good for? Can I clearly define it for a clinical trial and for a payer? Will the indicated population be clear to a physician? This is where the "unmet need" lies.
- What is the current diagnostic information, and what does my new diagnostic test add?
- With the new information, what should happen that didn't happen before? How often? How big of an impact will this have on health outcomes? Prove how the previously-defined unmet need has now been clinically "met."

The industry is plagued with a dreamy belief that it pays to fight the notion that evidence must go beyond "proof of concept" or "clinical validity." Pointing fingers at payers and asserting that their concerns lie only their financial bottom-line is superficial and misguided. Willingness to invest in the value of your technology, knowing how to do it, and working in collaboration and engagement with payers, will improve the rates of commercial success while improving the industry's relationship with the payer community.

The Solution

We challenge the industry to hold themselves accountable. Diagnostics are critically important to improving health outcomes and driving safe and efficacious patient management, so let's prove it. The industry should be willing to ask themselves these pivotal questions:

- Are we properly framing the time and investment required for commercial success with the investor community?
- Are we aligning our products to unmet need?
- Are we actively developing evidence of clinical utility?
- Are we proactively engaging stakeholders to facilitate open dialogue? ■

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References

1. For an FDA-approved in vitro diagnostic, the same logic often applies, because like the CLIA entry threshold, the FDA threshold for approval is likely less than payers require.

(2016). Assays of Genetic Expression in Tumor Tissue to Determine Prognosis in Breast Cancer Patients. CareFirst.

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