

Getting "PERSONALIZED"

Sure, there are reasons why personalized medicine hasn't taken off yet—but they're not the ones you might expect. Stop worrying about shrinking the market for your drug, and start figuring out how the "test and treat" business model works

By Peter Keeling & Mollie Roth

After a decade of hype and expectancy, personalized medicine is still in the process of "becoming." The science is there, but it's still in the process of being perfected. With new entrants such as Pfizer's Selzentry for CCR5 trophic HIV, and the relabeling of Warfarin to include genomic-dosing data, the industry is moving beyond the mere promise of targeted therapies—and thankfully, moving

the discussion beyond oncology and the over-hyped Herceptin case.

New York Times columnist Olivia Judson recently asked: So why hasn't personalized medicine yet hit it big? In part, it may be a simple matter of timing. In a *Spectrum* report, one industry commentator estimated that "[i]n 10 years, about 20 to 25 percent of new products in the pipeline will depend



to some degree on a related test.”

The greater problem, and perhaps the biggest barrier to realizing the promise of personalized medicine, might be perceptions about the potential of these drugs held by the pharma industry itself. Most companies have a difficult time seeing therapies targeted toward specific genotypes—which depend on diagnostics to guide prescribing decisions—as anything more than a way to enhance R&D productivity within the currently challenged “one-size-fits-all” model of drug development.

Somewhere along the way, the pharmaceutical industry decided that the market segmentation implicit in targeted therapies necessarily translates into fewer patients and, therefore, reduced returns. But in reality, personalized medicine has far greater potential and much broader applicability than just an R&D enhancement. The industry needs to overcome the divergent business models between pharma and the diagnostic industry, and learn how to harness the marketing dynamics embedded and largely unexplored within personalized medicine.

Pharma companies can go beyond viewing personalized medicine as just an R&D productivity tool to understanding how it can reshape market dynamics, alter a drug’s marketing trajectory, and drive sales—possibly even in the face of generics competition. In fact, if managed and positioned correctly, tailored therapeutics can even offer a return on investment (ROI) equal to drugs developed under the one-size-fits-all model.

Convergence: Mind the Gap

While many of the leading pharma and diagnostic companies have outwardly embraced the idea of personalized medicine, how to get such therapies translated into practice is a very different question. The two industries have developed very different business models, which are culturally, strategically, and



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financially distinct, and their junction during co-development and clinical decision-making is a much more difficult and complex prospect than simply working side-by-side.

The difficulty in working together is particularly exacerbated when dealing with personalized medicine, which requires the diagnostic and pharma industries to overcome not only a cultural and strategic divergence, but also a technological divergence of therapy and diagnostic. Historically, when the two industries have attempted to work together the results have been suboptimal. In one notable case, diagnostic and pharma companies agreed to co-develop and co-market a targeted therapy, but the diagnostic partner ultimately sued its pharma partner when it found out that drug reps were telling physicians that they didn’t need to use the test.

To make personalized medicine a reality, the pharmaceutical and diagnostic industries must learn to work together, as interdependent partners motivated around and by the same value proposition. Other industries have showed the value of this convergence. Take, for instance, the marriage of computing and hardware manufacturers like Nokia and Motorola, which have developed mobile-based television broadcasts. Companies such as these offer a good example of how integrated thinking and development processes can lead to coordinated, market-driving products.

Within the field of healthcare, other

prototypes of integrated development exist, such as drug-eluting stents for cardiovascular management and the integration of robotics and prosthetics. But these examples are not sufficient for most pharma companies. Time and again, executives and development teams brush aside analogies from other non-targeted drugs or other industries, asking, “What about other personalized medicines? How have they achieved this goal?”

The answer is that with only approximately 14 targeted therapies on the market across all disease areas, there are simply not enough examples from which to draw a roadmap sufficient enough to guide business practices and development decisions. Companies that wait for a well-traveled path built by their competitors will simply be the last to capitalize on the benefits of the new technology.

At present, the idea of developing and launching a test alongside a therapy is either resisted by the individual drug development teams or undertaken on an “if we have to” basis. One of the most common, self-limiting, and damaging ideas within drug development teams is the desire for a hands-off approach to a companion diagnostic strategy under the simple rationale that “we are not a diagnostic company.”

It remains to be seen whether pharma companies will acquire their diagnostic partners or continue to try and create strategic partnerships. Whatever the model, both sides need to learn how to integrate their divergent development and business models to effectively co-develop and launch personalized medicines.

