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Personalized Medicine: What's Your Strategy?

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Free content: Personalized medicine is upending the business of health care. In March, In Vivo will focus on exploring this new landscape. There is no single "right" route for companies to follow, but pharma, payers and other stakeholders need to find a path because the forces driving personalized medicine are global, and unstoppable.

Personalized medicine is on the rise. Genomic sequencing is allowing rapid, accurate analysis of our DNA, and uncovering the detailed fingerprints of diseases like cancer, which is now understood in terms of DNA mutation profiles rather than its location in the body. This is allowing the development of more targeted – and thus more effective – treatments, closely matched to patients' conditions. Targeted therapies mean fewer people suffer unnecessary side effects that may accompany ineffective therapy. They help payers avoid the costs of products that don't work and for pharmaceutical firms, they transform R&D economics: trials that select participants according to their genetic profile, to fit as closely as possible the therapy under study, generate results faster, with fewer patients, than those that don't.

The number of trials that include a companion diagnostic to help select eligible patients is growing steadily, from one trial in 1989 to 435 in 2015, according to Informa's Pharma Intelligence's *Trialtrove*. Most big pharma late-stage oncology development programs have a diagnostic. And since targeted drugs are likely to show strong efficacy in a specially-selected population, they also face a higher chance of approval. Indeed, the data show that targeted drugs are three times more likely to be approved than non-targeted drugs. The risks and costs of drug development are shifting radically.

But technology is also driving personalized medicine. Mobile phone apps and *FitBit*-style trackers allow us – and our doctors – to monitor multiple health parameters, including physical activity, mood, sleep and much more. These can help doctors identify how well a therapy is working, and to tailor dose, route of administration and support services (such as reminders) to individuals'

lifestyles and behavior. A young "gaming" fan, for instance, may respond best to medication management tips from an online avatar or something similar. Patients with diabetes can now measure their blood glucose simply by scanning a small wearable patch; others who have trouble remembering their medication may soon be able to have a year-long supply implanted under their skin and released as required. Sophisticated sensors and devices can more accurately diagnose and follow, in real time, the progress of multiple sclerosis patients – and adjust their treatment accordingly.

The scientific and technological forces driving the personalized medicine revolution are also driving – and demanding – radical change among health care stakeholders. Pharmaceutical firms are seizing the opportunity to change how they design, recruit and run clinical trials. They need new kinds of data and tools to find appropriate patients, and to set up multiple trial sites to access the patients they need. They must engage with new kinds of partners – diagnostics firms and patient-led organizations, but also innovative data analytics and technology groups, as well as consumer-focused experts.

The personalization of medicine opens up new opportunities for pharmaceutical firms to improve their productivity, profitability and public profile. Creating a personalized medicine doesn't in itself guarantee market access or higher sales. And it's unrealistic to assume that any payer will be able to afford a tailored treatment for each individual under its coverage, even if such solutions were available.

But if the business case for personalized medicine isn't exactly jumping off the page, it is becoming clearer. The reversing fortunes of two competing lung cancer drugs, one targeted, and one not, show how. *Bristol-Myers Squibb Co.*'s *Opdivo* (nivolumab) and *Merck & Co. Inc.*'s *Keytruda* (pembrolizumab) are similar, except that Keytruda requires patients to undergo a diagnostic test, and Opdivo doesn't. Since their US approvals in 2015, Opdivo has significantly outsold Merck's Keytruda, largely because using Opdivo avoids the hassle of testing, and the two drugs' efficacy appeared otherwise similar. But the tables turned in mid-2016 when Keytruda showed far better results than Opdivo in a first-line treatment setting. The drugs' sales trajectories have since reversed. Practical hurdles like testing can be overcome when they are shown to lead to better results.

This month, *In Vivo* devotes itself to exploring this new landscape. Just as no single medicine works for everyone, there will be no single "right" route for companies to follow. But ignoring personalized medicine would be a mistake. Systems, mind-sets and prevailing cultures take time to adapt to new technologies and solutions. Yet they will adapt, because the forces driving more personalized medicine – science, technology, the hunt for cost-effective outcomes, patients' and payers' demand for better quality, affordable care – are global, and unstoppable.