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Top health industry issues for life sciences in 2014

PwC's annual forecast of the year's most important healthcare trends

By Michael Swanick, PwC

Each fall, PwC's Health Research Institute (HRI) polls 1,000 consumers and interviews industry experts to identify the top health industry issues for the coming year. The scope of the survey ranges across the entire healthcare landscape, from manufacturers to providers to insurers and retailers. We've identified 10 key drivers of the overall landscape, many of which focus on how consumers engage with the health system.

Four of the 10 findings that we believe will directly impact pharma, biotech and device manufacturers (in no particular order) are:

- Corporate venture capital is picking up the slack as traditional venture funding slows for pharmaceutical start-ups
- Drugmakers must rethink their clinical trial research methods, embracing alternative approaches
- New regulation aims to eliminate counterfeit medications in the drug supply chain
- Social, mobile, analytics, and cloud technologies are driving new health industry business models.

Venture capital

As traditional venture firms pull away from funding life sciences start-ups, corporate capital will pick up the slack in 2014. Corporations are launching venture arms; they are involved in a growing share of healthcare deals. In recent years, corporate venture firms bet almost one in three dollars on life sciences' newcomers, investing more money in biotechnology than any other sector except software.

Start-ups should consider seeking corporate partners, which often offer longer investment horizons, industry connections, managerial expertise, skill navigating regulatory and reimbursement minefields, and marketing prowess. For smooth marriages, start-ups should consider how involved the new partners will be and how involved they want them to be.

Corporations should nourish healthcare product pipelines with corporate venture arms, which also will expose them to fresh ideas and talent. Through partnerships with traditional venture firms, corporations broaden their reach into start-up communities.

Clinical trials

It's hard to argue with 50 years of scientific achievements. The randomized, double-blinded, placebo-controlled clinical trial has had a remarkable run as a cornerstone of therapeutic and diagnostic development. In 2014, as the industry comes under increasing pressure to replenish its product pipeline faster and with fewer dollars, drugmakers must rethink their research methods. Alternative approaches that use consumer-generated data, adaptive design, and remote sensing technology will become more common.

In the year ahead, research insights drawn from consumer-generated data will play a bigger role in clinical trials. As new trial methods take shape, companies will increasingly need personnel who can design studies that evolve over time, incorporate new data, coordinate remote studies, and model outcomes. Nearly 70% of consumers surveyed by HRI agree that biomedical research is an important economic growth engine, but they are unsure of their role. Trial sponsors must make trial participation less taxing, more transparent, and convey better information about trial options, results, and how patients can participate.

Drug supply chain

The Drug Quality and Security Act, which passed Congress with bipartisan and widespread industry support, will be phased in over 10 years, culminating in an inter-operable, unit-level drug tracing system for the entire country. PwC estimates that the program will cost drugmakers $10 million to $50 million per manufacturer, depending on the size of the company and the complexity of its supply chain. Global firms will incur additional costs to comply with upcoming international standards.

To meet upcoming regulations, manufacturers should work closely with distributors and develop an open dialogue with regulators to guide and monitor changing requirements. This will be particularly important during the first year of the federal law's implementation.

Serialization and track and trace regulations in the pharmaceutical industry continue to be a global regulatory issue with local implications. Pharmaceutical companies will need a global, holistic strategy that they can also implement locally.

Pharmaceutical and biotech manufacturers should consider establishing executive-led governance structures focused on supply chain security and regulatory compliance. They should convene strong program management teams that will head up the initiative and engage key leaders across the organization to maintain a global focus on evolving regulations.

(Continued)

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Mobile health

While the health industry has dabbled in social, mobile, analytics, and cloud technologies during the past few years, many organizations have failed to connect them to the major information systems they use to run their businesses—electronic health records (EHRs), research and development systems, and member and sales management systems used by insurers and retail pharmacies.

Drug and device companies should enhance their understanding of what drives consumer behavior and satisfaction as consumers become more brand-aware through their interaction with smartphone apps and social media sites. PCm

ABOUT THE AUTHOR

Michael Swanick is the global leader of PwC's pharmaceuticals and life sciences practice, part of PwC's Health Industries Group, a leading advisor to public and private organizations across the entire health industries landscape. This group also includes PwC's Health Research Institute, which provides new intelligence, perspectives, and analysis on trends affecting health-related industries. The comments above are excerpted from PwC's Health Research Institute's *Top Health Industry Issues for 2014* report, available at www.pwc.com/us/tophealthissues.