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Forging *New* PATHS

Ever-changing market dynamics will create an industry that is unlike the one we have today.

2013 promises to be as tumultuous as 2012, as the industry looks to contend with the political ping-pong ball that is healthcare. Faced with myriad internal and external pressures, life-sciences companies of all types and sizes will need to address a growing stakeholder base that is better informed and better armed to make far-reaching decisions that could potentially impact the industry for years to come. They will also have to streamline how they develop and commercialize their products and improve the value provided to the overall healthcare system, while enhancing operating efficiencies.

Jade Cusick, president of U.S. marketing insights at Kantar Health, says the growing oversight and power of regulatory and payer bodies and their increased focus on not only value but affordability, along with an increasingly more informed and engaged consumer, will continue to represent the most significant forces acting on the global healthcare environment.

"Too often the future implications of all stakeholders' needs and likely actions are not considered early enough in the development life cycle," he says. "For example, new product forecasts, if possible, should include dynamically linked modeling to simulate the impact of payers' likely reimbursement/restriction position, along with the growing impact of cost shifting to patients to truly understand the long-term effect on uptake and use. Those companies that invest earlier in understanding the interconnected needs of all key stakeholders will be at a distinct advantage in not only delivering more accurate forecasts, as in this example, but ultimately making smarter developmental decisions that will result in more long-term value."

One of the ways companies may choose to engage with all of the different stakeholders is through field-based and in-house medical affairs groups, according to Evan Demestihas, M.D., R.Ph., CEO of The Medical Affairs Company. He says these individuals are able to engage in unbiased, peer-to-peer, scientifically focused discussions with a host of healthcare professionals, which can range from top-tier academic thought leaders requiring high-level, scientific exchanges specific to their therapeutic area of expertise, to payer audiences requiring budget impact and burden of illness economic modeling presentations that incorporate clinical outcomes and quality of life issues.

Beth Price, executive VP, The Medical Affairs Company, says expanding role of medical affairs is largely a result of practicing physician's desire to be and remain more clinically aware and educated about new treatment concepts and advances in other words the "cutting edge."

Additionally, experts say as the industry moves from a fee-for-service to a fee-for-value model, companies will need not just to tell a powerful clinical story but an equally effective economic story. This will be particularly true for more expensive therapies, such as biologics.

R&D Trends

Large and small biopharma companies are seeking to increase the efficiency and productivity of their R&D functions. They are collaborating with nontraditional partners, gathering insights from observational studies, and leveraging analytics to increase throughput of the clinical development process.

Our experts say innovation in R&D is going beyond the science to tools, process, technologies, and the operating models that result in higher productivity, global collaboration, and better decision-making throughout the R&D cycle.

The emergence of new forms of collaboration and open innovation models will be an important part of improving the efficiency of R&D through greater standardization and reduced duplication of efforts.

Another major area for innovation and new technologies is in drug discovery, including advances in improving validation of gene-disease associations and providing new insights and information to analyze the complexities in human physiology. Pharma companies are working with partners to build data-driven computer models to understand disease, develop biomodels, and to discover biomarkers for patient selection and even to predict the efficacy of drug combinations.

Our experts also say powerful technology will make development processes more efficient. Companies are looking to centralized and easy-to-set-up and manage portals because clinical trials are becoming increasingly complex and global in nature. But they will need to reshape how their organizations work in this

Biotech In Action

In the biotech arena, the global industry showed a second straight year of increasingly stable financial performance in 2011, according to a recent E&Y report. Established biotech markets registered more than 10% revenue growth for the first time since the start of the global financial crisis. But longer-term sustainability remains challenging, with the traditional funding and innovation model for precommercial biotech firms under unprecedented strain.

"With investor-provided capital unlikely to increase in the near term and a decline in the size of up-front payments from pharma companies in collaboration arrangements, biotech companies are focused on capital efficiency in all areas — from the size of their organization and infrastructure to the therapeutic areas they are pursing," says Glen Giovannetti, global life sciences leader at EY.

fast-changing, dynamic, and global industry. Leadership, process changes, and adoption of flexible platforms must be combined to more effectively manage global clinical trial programs.

The era of big data is here, and here to stay. There is an immeasurable amount of data, and to manage it effectively, the industry will need to look toward the cloud, our experts say. When used simply for data storage, the cloud was thought to be a way to cut costs, but now the thinking has advanced to include how to use the data to increase revenue, ensure compliance, and ensure stakeholders' interests are being met.

According to Dave Espenshade, senior VP of sales and marketing, Y-Prime Technologies, the use of cloud-based systems to support clinical trials is most successful when sponsors are willing to accept standard features and functions and that increasingly, sponsors are seeing the value of implementing an entry portal that serves as the landing space for all users of cloud solutions. This single point of entry also facilitates compliance.

This will be extremely critical as the industry continues to seek out global markets. From changing demographics, emerging markets increasing in influence, and an increasing focus on both biotech products and generics, pharmaceutical companies will see a changing market globally. Our experts say it will be necessary to create partnerships with stakeholders in global pharma products to ensure success. As leaders broaden their engagement of the global scientific community, expect to see a more open environment globally.

But as the industry becomes more global, regulatory compliance becomes more complex. Global health authorities are looking for a comprehensive risk management plan that includes not only all of the elements of regulatory compliance, but ties to the company's plan for sales, marketing, and overall brand protection.

Our experts expect deeper involvement by the regulatory professionals in the overall product launch strategy earlier in the development stages of the product. This, they say, helps companies demonstrate to health authorities the company's commitment to the safety of the consumer.

Social Media Trends

With all of the data now available about how physician audiences are using smartphones, the industry needs to provide the tools and information that physicians are seeking. According to Darlene Dobry, president, Ogilvy CommonHealth Medical Marketing, part of Ogilvy CommonHealth Worldwide, this includes: access to the most critical brand information, apps that actually serve a purpose and help the physician to efficiently tap into data or provide patient education, the ability to transfer information to other stakeholders in the continuum of care, a hassle-free registration of patients into patient support/reimbursement programs, plan access information, informatics and telehealth vehicles for patient care, and monitoring and follow-up.

Todd Zander, VP of product management, application design and innovation, at WebMd, believes mobile apps have tremendous potential for pharmaceutical companies to directly reach the targeted audiences they are seeking.

"Companies with existing relationships with consumers and physicians across a multiscreen platform can easily extend online campaigns into mobile and expand a brand's reach to their target audience," he says. "Pharmaceutical brands can also take advantage of a variety of digital assets on a mobile platform, including video and slideshows, with customized mobile media and sponsorship products."

Marketing Trends

In the marketing arena, pharmaceutical companies have been increasing their investment in digital marketing strategies over the past three years, and growth trends indicate that certain digital channels will soon surpass more traditional media tools. There are several elements to getting the most out of the various digital channels and the interactions they offer, our experts say. One is to understand how consumers will be using the data, and how to align their behaviors and digital use with business objectives.

Barry Schmader, executive VP, chief creative officer, Dudnyk, says strategies will need to focus more on engagement than on the traditional awareness and persuasion model of communications.

"But different targets will each contribute somewhat divergent strategic branding challenges," he adds. "For the patient and consumer audiences, the challenge will lie in taking advantage of the opportunity provided by multichannel marketing, a buzzword that means nothing more than the explosion in media options that is revolutionizing the way people receive messages from marketers. There is opportunity in the excitement and personalized nature of communicating through devices that people now hold so close — in their hands, in their pocket, or in their consciousness all day long."

When it comes to DTC in the 21st century, small is the new big, our experts say. The circumstances in which ad campaigns are planned have changed — technology has sped up the entire process, and digital channels provide quick response and access to a more targeted audience.

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JADE CUSICK / Kantar Health

Advertising strategies of the future will likely be more direct response in nature, containing things such as vanity website URLs and QR codes to move the reader directly from an offline to an online environment.

These types of new technologies are not only enabling greater access to information, they are better capturing the attention and imagination of specialty audiences. Social channels are letting niche brands take part in and influence the online dialogues with patients and caregivers. PV

A Shift in the Model

Mike Haley, VP of life sciences at Genpact, says the changing business environment in the industry is driving the shift in the selling model from traditional wholesale models to end-user distributors. Pharmaceutical and device manufacturers are now starting to contract directly with the end-user distributor; retail pharmacies, pharmacy benefits managers and large healthcare systems.

Revenue leakage costs life-sciences companies an estimated $11 billion (more than 4% of revenue) annually, Mr. Haley says.

"This problem persists because of the lack of comprehensive contract management standardization and quality processes," he says.