Getting Down to BUSINESS

Focusing on the patient is mission critical as the industry undergoes a transformation to prepare itself to deliver on a pill-plus-service model.

In this annual special issue, experts representing all aspects of the life-sciences industry provide their insights and predictions on the trends, challenges, and opportunities facing their companies and the overall ecosystem in the coming year.

In reviewing the multitude of responses to our call to action, several themes emerged, which we will explore in depth throughout the issue. To highlight just a few, across the board there is agreement that there needs to be a focus on the patient and away from the pill. We identified this as a trend several years ago starting with a shift in the business model. Today, patient centricity is no longer just being viewed as a commercial opportunity; there is a view to keep patients front and center — where they should be — in every aspect of the continuum. And as this trend threads out, we are hearing how companies are innovating and setting new objectives and metrics to align with this "new" focus.

With R&D productivity at the lowest it has been in 15 years, our experts say it's time for some radical changes. According to Cognizant, for the fifth year in a row sales for every $1 billion in R&D has come down 70% from $275 million to $75 million. At the same time, the cost to bring an approved molecule to market has quadrupled from $500 million to almost $2 billion.

But at the same time Cognizant analysts see that there is hope on the horizon, with late-stage pipelines showing more promise than they have in the past 10 years.

Setting the Right Objectives for 2014

"Our industry is entering a watershed year," says John Doyle, senior VP and managing director, global market access, of Quintiles. "For decades, healthcare stakeholders have operated in a state of quasi-isolation, relying on their own processes, skills, and intellectual property to deliver stand-alone solutions. As health reform continues to catalyze changes in healthcare, it precipitates a new integrated model that encompasses the entire healthcare continuum and coordinates the drive toward the triple aim of improving population outcomes, enhancing the quality of care, and driving down cost. All stakeholders need to think holistically about their impact on population health and engage in partnerships that can deliver product and services to improve healthcare system performance.

> "The most critical business objective is to ensure our industry's value and importance to biomedical innovation is embraced and guarded."
>
> **NICK COLUCCI**
> Publicis Healthcare Group

According to Manish Soman, CEO of Sciformix Corp., there are three key business objectives that need to be addressed over the next few years and significant progress will have to be made in 2014 toward achieving them.

"Bringing down the cost of healthcare by optimizing discovery, development, commercialization, and maintenance of healthcare products is imperative," he says. "It's also important that the industry enhance the safety of products by more efficient and pro-active safety and risk management solutions. And, we need to design technology-based solutions to bring about better collaboration between patients, physicians, payers, and regulators to improve healthcare research and delivery, and optimize costs."

Bhaskar Sambasivan, VP and head of life sciences at Cognizant, agrees that lowering the cost of R&D operations is critical and suggests that improvements can be made through at-scale outsourcing, risk-based and remote monitoring, and the use of new mobile enabled patient-centric technologies, which he says can bring down the cost of a trial by up to 30%.

> "The industry needs to optimize clinical trial operations through technology."
>
> **ERIC SILBERSTEIN**
> TrialNetworks

> "The life-sciences company that can transform itself from a great manufacturer of products to a valued stakeholder to achieve better outcomes will ultimately win."
>
> **DAVE ESCALANTE**
> Cegedim Relationship Management

Advancing the pipeline of drugs and therapies in development on time, on budget, with the requisite quality and with the ultimate goal of getting new and better medicines to patients worldwide remains the ultimate priority across the industry.

"As a CRO, our objective is to help customers do this more efficiently and effectively through streamlined processes, strong site engagement, and new and better technologies," says Jamie Macdonald, CEO, INC Research.

According to Glen Giovannetti, global life sciences leader, EY, there are four objectives that have to be on the C-suite agenda for 2014: addressing the growing challenge of chronic diseases, extending business models with more patient-centric value propositions, finding new ways to demonstrate — and deliver — value, and having a clearly defined transaction strategy to drive growth value.

"Compliance is also becoming an increasing concern as the risk environment — and the ability to mitigate risk — continues to grow in complexity," he says.

Dr. Marc Bonnefoi, head of the North American R&D Hub at Sanofi, identifies four key priorities that his company is focusing on for 2014: being a global healthcare leader with synergistic platforms, bringing innovative products to the market, seizing value-enhancing growth opportunities, and adapting the structure for future challenges and opportunities.

"Sanofi is focused on seven strategic growth platforms of diabetes, vaccines, consumer healthcare, rare diseases and multiple sclerosis, other innovative products, animal health, and emerging markets," Dr. Bonnefoi says. "Not only will these enable us to improve access to quality healthcare and meet unmet needs, but they will also deliver the sustainable growth required to allow us to continue to invest in innovative research & development."

According to Dr. Bonnefoi, R&D has always been and will continue to be the cornerstone of the company.

"Sanofi has built a revitalized R&D organization centered on patients' needs and delivering truly innovative solutions," he says. "To achieve this we are putting the patient at the center, focusing on better understanding the biology of disease, selecting targets that matter relative to human translation, and developing integrated solutions."

Dave Escalante, senior VP, OneKey and marketing, Cegedim Relationship Management, says the life-sciences industry will need to continue to evolve.

"For the life sciences, these forces will impact the entire value chain, from R&D to marketing to sales," he says. "The life-sciences company that can transform itself from a great manufacturer of products to a valued stakeholder to achieve better outcomes will ultimately win. The challenge for my company will be to deliver the right technology, information, and services to help our customers better understand, gain unique insight, define and deliver new commercial strategies in order to help fuel the transformation."

Big Data

The big data promise will become a reality through the application of data and related analytics across the full value chain of drug promotion.

"This wave will impact everything from enabling hyper-targeted patient selection for trials to having iterative drug discovery pipelines automate the selection and testing of early stage compounds," says Tom Arneman, president of Ceiba Solutions.

According to Patrick Homer, principal industry consultant, global practice, health and life sciences, SAS, the industry is emerging from a decade of stripping out costs and is now poised for building the foundations of the new commercial model.

"There has been much research published on the role that analytics can play by increasing the productivity of organizations up to 6%," he says. "For the life-sciences industry these gains can be captured in many areas, such as increasing the capabilities in segmentation, global pricing decisions, and inventory management."

To tackle the challenge of increasing productivity through analytics, Mr. Homer says life-science organizations need to think about how they prioritize these capabilities.

"What data do they have and what other data could be available to deliver better answers?," he asks. "How should they modernize their analytic infrastructure to deliver fast answers that allow scenario simulation? What types of analytics do they need — predictive modeling/optimization/demand forecasting? And, most importantly how do they drive the required behavioral change throughout the organization?"

> **"Some companies are realizing that they don't have the required level of expertise internally to provide adequate oversight to the outsourced work, so core competencies are being redefined."**
>
> **MANISH SOMAN** / Sciformix

Ruth McHenry, managing director at Infinata, says everyone needs to make market predictions based on the data available, but it's not enough to just gather data — it has to be useful.

"Adding a layer of strategic analysis and intelligent algorithms to predict drug approvals, identify statistical probabilities of phase advancement, and anticipate market shifts can be the difference between winning and losing," she says.

Big data and analytics also have critical applicability to the sales rep to physician relationship.

"As physician offices are increasingly limiting sales rep office visits, sales reps are under greater pressure than ever to make the most of each office visit and interaction," says Erin Byrne, chief engagement officer, ghg. "The use of closed-loop marketing or CLM platforms that tie together presentations with data to deliver a customized experience can change the dynamic of the office visit. Today a sales rep can record the nature of a visit with sales management software and take notes on concerns or issues raised during a visit. The rep may even be able to send an automated email after the visit to follow up on outstanding issues. But the next level of the sales rep interaction will incorporate better mobile use strategy. New CLM platforms will incorporate the physician's profile on brand websites, his activity on a brand's Facebook page and other social media relevant to the brand. This collection of data will give the sales rep a better picture of what the doctor does online and what content motivates him or her to action. This is measurable and actionable information that can inform and elevate the conversation between the rep and the physician."

"Physicians increasingly expect information provided to them to be tailored specifically to their individual interests and needs," she continues. "The reality is that physicians have adopted a multi-screen work mode. They use desktops, laptops, tablets, and smartphones to access information in the delivery of care to patients. And they expect to have the same experience online regardless of the device they use to access content. To ensure this consistency across devices, brands must think about how physicians are using digital tools and adapt to their needs. For example, brands must build tools using responsive design to create experiences that are scalable across platforms and elevate the most relevant content given the device being used. Research shows that 57% of users will not recommend a business with a poorly designed mobile site. Responsive design ensures that a website delivers the right experience on all devices."

Outsourcing: Collaboration is Key

According to Mr. Doyle, the overarching healthcare market theme will be one of interoperability — connecting stakeholders and information sources in novel ways to optimize the public health impact by driving efficiency, effectiveness, and equity in the system.

"Health reform continues to accelerate this transformation and catalyze connectivity between various players by encouraging health information technology investment, forging quality-base payment models, and rewarding care coordination," he says. "These structural system changes require framing the market as a network of interconnected components, including products and related services, centered on the patient. This plan requires working collaboratively to channel the collective expertise toward common goals that will improve population outcomes."

Phil Birch, senior VP, global strategic marketing, Aptiv Solutions, says because of a series of regulatory changes and shifting demands by investors means that, particularly for medical device developers and midsize pharma, 2014 is the year that better development decision-making coupled with an initiative to drive cost-efficiency has to be at the top of the C-suite agenda.

"Both are achievable," he says. "Very encouragingly, we are already seeing a number of forward-thinking executives and investors move whole companies into portfolio-wide implementation of adaptive trial designs, not just for early termination for futility to curb financial loss, but as a business strategy to increase development success metrics, productivity, and portfolio valuation. Smart companies will apply adaptive design more widely in exploratory development and the first-movers will lead their organizations far ahead of the pack by the end of 2014. Additionally, significant cost-saving initiatives, such as risk-based monitoring championed by TransCelerate Biopharma and many other organizations will continue to progress. While there is a lot of hype about risk-based monitoring, implementable practical solutions will become available and take center stage in driving clinical trial monitoring costs down by 30% to 40%."

A recent Tufts CSDD Report found that collaboration is the key to R&D productivity. Alliances, collaborations, and consortia will continue to drive improvements in clinical success, while reducing total spending, with drug developers retaining only those functions they consider core competencies.

To succeed in delivering future innovative solutions, Sanofi is looking outside at partnerships and acquisitions.

"We have been successful in searching out the best science and the best companies to acquire and partner with, and we will continue to look for opportunities," Dr. Bonnefoi says. "We cannot do this alone. We aim for establishing relationships with our partners, not speed dating."

Mr. Soman says in the areas of development operations and life-cycle maintenance, several large pharma companies have recently defined — or in some cases, redefined — their outsourcing strategies and have entered into long-term strategic relationships with a few chosen vendors.

"The companies that did this a few years back may want to refine their approach based on their experience," he says. "Some companies are realizing that they don't have the required level of expertise internally to provide adequate oversight to the outsourced work, so core competencies are being redefined. This is


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"As drug-candidate promotion remains a core emphasis of the life-sciences industry, recent developments in data accessibility and processing will lead to massive innovations in this process through 2014."

TOM ARNEMAN / Ceiba Solutions

"We need to modify communications that recognize the challenge of the shift of control from physicians to payers and patients."

MARY ANNE GREENBERG
Ashfield Commercial

likely to pan out in the coming year. Some of the midsize to small companies are likely to look for an optimal hybrid model of partnering with full-service CROs, functional service providers, and scientific process organizations for specific functional areas."

Such collaborations, Mr. Soman says, will certainly increase and existing ones will have to become more impactful to address the continuing R&D productivity pressures.

"These collaborations help the sponsor organizations to redirect their internal focus to the more meaningful business areas and allow the non-core activities to be delivered by companies that specialize in these and, hence, provide a win-win situation," he says. "Going forward, these collaborations will focus more on operational efficiencies. We foresee that emphasis on process improvements, lean methodology, and automation will drive many of these collaborative processes."

Eric Silberstein, co-founder and CEO of TrialNetworks, also believes that the industry needs to optimize clinical trial operations through technology.

"Trials are essential to bringing new therapies to patients," he says. "The cost and complexity of trials means that life-sciences organizations are severely limited in the number of hypotheses they can test in the clinic and the speed at which they can receive results. Outsourcing alone has failed to deliver — the solution is to use technology to bring radical efficiency gains to clinical trials."

Mr. Macdonald agrees that planning and design of clinical trials is becoming increasingly important.

"We need to invest more time up front ensuring protocols are operationally robust and execution plans are realistic and achievable," he says. "As new technologies and more effective ways of doing business are introduced, sponsors and CROs need to be aligned and work together to truly drive innovation and efficiency in clinical development."

Mr. Soman says pharma companies are also looking for increased sophistication in terms of domain and therapeutic area expertise from their partners.

"This is in view of their strategic focus on certain TAs and the increased complexities of the drug development programs, as well as the increasing number of biologicals," he says. "Hence striking the balance between providing such expertise and also delivering on operational efficiencies will be the most significant challenge for all stakeholders in 2014. This will also shape the collaboration approach in terms of the mix of CROs and FSPs — BPOs, KPOs, and SPOs."

Most experts agree that driving increased efficiency and effectiveness of resource allocation across R&D and commercial operations is one of the key business objectives for 2014 and forward.

"Because the majority of large disease categories, for example hypertension and high cholesterol, have been addressed, this will become even more important as many new drug therapies are targeting smaller patient populations or are being used as second- or third-line treatment therapies for disease categories with significant patient numbers," says Brad Sitler, principal industry consultant, SAS Center for Health Analytics and Insights. "Embracing smaller brands and brands with lower pricing points resulting in smaller top-line sales revenue requires a more efficient spend of resources, both financial and human capital, to deliver the same net revenue back to the business."

Innovation Leading the Way

Daniel Teper, CEO of Immune Pharmaceuticals, says the life-sciences industry needs to regain a leadership position in terms of positive contribution to society, particularly in terms of innovation.

"In Forbes' ranking of top 100 most innovative companies there are two biotech companies — Alexion at No. 2 and Regeneron at No. 4; there was no big pharma company," he says. "Is biotech the future of pharma? Companies will need to make a clear choice between the diversified conglomerate model, such as Johnson & Johnson, and the specialty model, such as Gilead. In the conglomerate model, the focus should be on commercialization and M&A of late-stage development or commercial-stage companies. The specialty companies will drive innovation and will increasingly develop commercial capabilities to create more cutting-edge therapies."

Richie Etwaru, group VP, clouding and digital innovation, at Cegedim, also questions the current business model adding that life-sciences companies will need to move from an existing vertical organizational design, where vertical groups are aligned along products or regions to a horizontal design, where horizontal groups are aligned with key functional areas and can control mechanisms.

"A horizontal design will install efficiencies, create cost-savings, consolidate and reduce risk, drive collaboration, and enable agility," he says. "Given the concurrency and magnitude of macro strains, including constricting margins doubled over with reducing revenue, a leaner and more agile life-sciences organization is the path to survival and vehicle for successful M&A activity."

Nick Colucci, CEO of Publicis Healthcare Communications Group, says the most critical business objective is to ensure the industry's value and importance to biomedical innovation is embraced and guarded.

"Health is a societal unifier, and, like the need for water, it is a life essential," he says. "Certainly, the absence of health draws in families, physicians, and governments, resulting in anguish, cost, or societal burden. In the face of challenges around access to care, cost, and compliance, we must find ways for client brands to be recognized as necessary in peoples' lives. Patients, caregivers, physicians, and policymakers ultimately look to medicine to help guard health or return to health. Communications is a critical part of the care process."

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> **"The industry is emerging from a decade of stripping out costs and is now poised for building the foundations of the new commercial model."**
>
> **PATRICK HOMER** / SAS

> **"We have a responsibility to improve access to medicines and quality healthcare."**
>
> **DR. MARC BONNEFOI** / Sanofi

Mary Anne Greenberg, regional president for North America at Ashfield Commercial, agrees that the industry needs to modify its communications to recognize the shift of control from physicians to payers and patients.

"We have found that the strategy needs to center not on individual services but a business model that allows extraordinary collaboration to improve patient and healthcare practitioner behaviors that lead to better outcomes. Some examples of such collaborative efforts would include teaming nurses in the field and our call center to help patients take ownership of their health by providing the right amount of education and support based on individual patient's needs. Carrying serialization numbers from medical information or customer services into a drug safety database can help ensure product authenticity and align the medication journey. Another examples is deploying field sales and insides sales teams to be strategically aligned with formulary approvals and changes to address payers."

Mr. Arneman says the role of innovation will shift from idea creation to execution.

"Biopharma will begin executing on existing concepts of patient-focused innovations to make them realities," he says. "Perhaps surprisingly, the ones that succeed may partner with more agile external partners to accelerate and own the development of the idea to realization."

Mr. Colucci says patients need to think about navigating their way from sickness to health, and communication is a roadmap supporting their journey.

"We need to mobilize our expertise and capabilities to help client brands express value across audiences and geography," he says. "However, innovation depends upon collaboration — the challenges of healthcare are too complex to be resolved by one person or one discipline. We must organize and express great ideas across tactical channels. At PHCG, we pull together creative, digital, and channel expertise to deliver life-changing experiences for consumers and health professionals worldwide."

Life-sciences companies will need to adapt their own models as well as know how to fit into the business models of other companies that are closer to the patient.

"They will need to move beyond the product into the relatively unfamiliar realm of interactive relationships, customer segmentation, information services, and solutions," Mr. Giovannetti says. "This includes shifting from a business model based on one-off product transactions to one based on continuous relationships with patients. Many of the trends driving this change have also impacted other sectors — newspaper, commercial banking, electronic gaming, retail trade — that can provide examples and relevant insights for life-sciences companies."

Maximizing access for the newly launched product through demonstrable patient outcomes is critical, Cognizant's Mr. Sambasivan says.

"This will call for a shift from a pure product focus to a product and service focus," he says. "Great launches will have an integrated strategy that for their chosen disease areas, can help improve patient outcomes, lower cost of care, and enhance patient experience."

Along the lines of patient-centricity, Mark Taggart, head of patient reminders at Cenduit, says the most important business objective for the life-sciences industry should be to implement a more proactive approach to patient retention and compliance.

HOT TOPICS

RICK KEEFER
President and CEO
Publicis Touchpoint Solutions

ACA

In addition to all the market turbulence over the last few years, our industry now needs to navigate the market disruption caused by the Affordable Care Act (ACA). As this new healthcare law goes into effect, previously uninsured patients will enter physicians' offices. HCPs will find their patient loads increasing, and focus will shift from treatment and fee-for-service to prevention and fee-for-outcomes. As the healthcare business model shifts toward disease prevention and health outcomes, our industry can serve a crucial role in facilitating connectivity between HCPs, patients, caregivers, managed markets, hospital systems, and other players. Approaches that address the inherent breakdowns in transitional care offer enormous opportunities to provide value that can impact every stakeholder. An example of this can be seen in the growth of clinical health educators who play a critical role in improving health outcomes.

BRAD SITLER
Principal Industry Consultant
SAS Center for Health Analytics and Insights

ACO

The life-sciences industry needs to redefine, or develop in the case of ACOs, a commercial model for payers, providers, and ACOs that reflects the new healthcare market place driven by the Accountable Care Act. As the ACA is based upon a fee for value approach to healthcare, payers, providers, and ACOs are taking on new levels of risk for member or patient outcomes. The pharma company that can either demonstrate that its brand provides for either improved outcomes and/or similar outcomes with a lower total cost-of-care when compared with the competitors will thrive. That said, proving these improved outcomes or a lower total cost-of-care will require significant transparency in data and analysis as providers and payers will also have access to large state, regional, or national healthcare.

KEVIN LAI
Director Biomedical Sciences
Singapore Economic Development Board

Asia

Despite the huge growth opportunities Asia presents, companies are challenged by the heterogeneous and fast-evolving healthcare policy and regulations across Asian nations, which have posed new challenges for countries looking to access markets in Asia. That said, we see companies shifting more resources to Asia and putting in place long-term strategies to win in this market.

MARK TAGGART
Head of Patient Reminders
Cenduit

Compliance

I can't wait for the day when the smartphone industry creates a Jelly Bean dispenser. Every positive episode of compliance should be rewarded with love. Patients are humans after all, and they should be treated as such. It is great to see the shift within the industry to a more patient-centric way of conducting clinical trials. As we shift our focus to the site and the patient, we'll move more quickly and effectively to our end goal of furthering science and improving lives.

ABRAHAM GUTMAN
CEO
AG Mednet

Data Management

The industry needs to think hard and fast about ways to manage the convergence of data emanating from dissimilar sources — genomics, proteomics, and imaging — to find better pathways leading to better treatments. Existing tools that work very well in Phase II and III studies are not adequate to handle the more fundamental questions and analyses required to determine if a particular therapy is worth the investment cost.

DAVID SHOEMAKER
Senior VP R&D
Rho CRO

Integration

The top business objective will be to integrate disciplinary development efforts earlier to enable companies to bring more products to market sooner. The industry is still predominately working in silos with companies applying marketing goals, regulatory requirements, and reimbursement strategies too late in the development process and without regard to constantly changing environments. Companies that begin to plan on these three fronts simultaneously in early development stages will be the most successful in today's environment and the future.

GLEN GIOVANNETTI
Global Life Sciences Leader
EY

M&A

With the life-sciences industry anticipated to be one of the most acquisitive in 2014, upgrading product and business portfolios through acquisitions will continue to be a core strategic tool for achieving growth ambitions, and rigorous integration planning is more important than ever. Pruning the portfolio is equally important, to free up capital and help focus on the highest potential investment opportunities. Divesting to maximize value is quickly becoming a mandatory core competency.

GLEN DE VRIES
President
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Mobile Technologies

The future is now. For the past few years, our industry has continued to talk about the need to redesign clinical trials, accelerate pharma's pipeline decisions, and improve time to market, and how mobile technologies will allow for new kinds of interactions between pharma, physicians, and patients. 2014 will be the year that this starts to happen at scale. Leveraging their own smartphones and global network infrastructure that has become as commonplace as basic telephone service, study participants will push patient reported outcomes directly to study databases, link their mHealth devices to automatically upload in-home, real-life data, and connect with physicians, nurses — perhaps even pharmacists —in new ways to improve recruiting and engagement. All of these new models won't be successful, but creating a critical mass of experimentation will mark a significant milestone as patient engagement becomes an integral, and essential, discipline in the life sciences.

RICK MORRISON
Founder
Comprehend Systems

Risk-Based Monitoring

Risk-based monitoring and centralized analysis will drive the industry in 2014. Both trends are critical to enabling every person involved with a clinical study has the answers they need to do their job, ideally in real time, with up-to-the-minute answers.

Companies are trying to build data warehouses, but they fundamentally do not work for clinical data. Data warehouses work well when the underlying data sources don't change, like in a manufacturing plant, but they fundamentally don't work in the life sciences, where studies change or new studies come online regularly. Data warehouses are primarily used as a platform to sell professional services, which includes functionalities that simply don't align with the life-science industry objectives and demands.

BRIAN KLEPPER, PH.D.
Principal
Healthcare Performance Inc.

Risk Reward

The life-sciences industry's most important objectives will be to adapt to the health industry's drive toward risk and away from fee-for-service reimbursement. While the transition will take time, this orientation will be a dramatically disruptive innovation, presenting the industry with the problems and opportunities associated with changing care and cost patterns.

Evidence-based practice will become more widespread, favoring high-value agents and disrupting those with marginal efficacy.

Risk will also create immense opportunities to assist clinicians in managing the complex interactions among multiple agents. Better pharmacologic coordination will yield better, more efficient health outcomes, and prove winning for care delivery organizations. The industry has both the resources and expertise to develop advanced management capabilities that have been clinically needed but less desirable under fee-for-service.

"The reality is that physicians have adopted a multi-screen work mode. They use desktops, laptops, tablets, and smartphones to access information in the delivery of care to patients."

ERIN BYRNE / ghg

"The most forward-thinking drug development companies know that almost all studies will inevitably have a patient compliance, adherence or retention challenge," he says. "However, only a few companies in the industry are currently addressing this issue. Patients don't mean to be noncompliant. They are just like us, often stressed, and lead busy lives. In addition, they may be enthusiastic about the clinical trial at the start, but their interest and motivation can wear thin over time. Sponsor companies that implement an action plan before study start can save millions and reduce study risk significantly."

Outcomes continues to be a prevailing theme and the focus on improving patient outcomes will continue throughout 2014.

"The life-sciences industry needs to transform itself from just treating disease to managing health and demonstrating improved outcomes," says Sheila Rocchio, VP, marketing and product management, at PHT Corp. "Life-sciences companies need to become more patient-centric in all aspects of their approach to drug development. New trial platforms that use the ePRO provisioning model will pave the way for more BYOD — bring your own device — trials. BYOD will be a huge part of healthcare and a major platform for interacting with patients."

Ms. Rocchio adds that people perceive the FDA and other regulatory bodies as the most important customer in clinical research and while the regulators are critical to the approval and safety of new medicines, the key customer is ultimately the patient taking the therapy.

"In terms of drug development the pharmaceutical industry needs to be a lot more innovative in moving away from paper, embracing technology, and thinking about the patient as the customer from discovery through marketing," Ms. Rocchio.

Mr. Giovannetti believes that healthcare costs are becoming unsustainable and adds that this in a large part due to a chronic disease epidemic fueled by unhealthy lifestyles and behaviors.

"For life-sciences companies, this means going beyond developing products to combat disease," he says. "More and more emphasis will need to be on figuring out interventions and incentives that can effectively change unhealthy behaviors. To do this, life-sciences companies increasingly need to develop business models that encompass not just the cycle of care but the life cycle of the patient to better understand the patient and what drives behavior."

Mr. Arneman says central to any transformation is leadership. The greatest impact will result from the continued promotion and development of leadership that understands the urgency of value creation for their organization and the ability to manage change.

"CEOs must drive innovation in the product portfolio and R&D via force multiplication of their management teams, but hold themselves responsible to their respective organization's redesign; as in many cases, this is a foreign construct to life sciences," Mr. Etwaru says.

One company that has undergone a redesign of its R&D structure is Sanofi.

According to Dr. Bonnefoi, Sanofi has undergone a deep organizational transformation, which has included a complete restructure of R&D, the expansion of its footprint in biotechnology through the acquisition of Genzyme, and refocused regional and global operations

"The creation of the hubs allows us to be ready to meet the next challenge and opportunity around the corner," he says.

Another company focusing on innovation is Cubist, and its Executive VP of Research and Development and Chief Scientific Officer Steven Gilman, Ph.D., says the most important business objective for the life-sciences industry for 2014 will be to continue to reinvigorate innovation and bolster investor confidence.

"With respect to Cubist specifically, we continue to invest significantly in discovery and development programs, which include addressing the growing global health threat of antibiotic resistance and rising hospital-acquired infections," he says. "While we have benefited by recently implemented legislation and policies, additional and more flexible regulatory approaches and economic incentives are needed to restore the pipeline. This is especially important as many larger biopharmaceutical companies have reduced or eliminated investments in antibiotics, or have exited the industry altogether."

Mr. Arneman says developing a clear understanding of the roles of trusted partners will help reduce costs and increase productivity. The emphasis of "outsourcing" practices will shift from cost-based to value-based, with the pendulum swinging back to smaller trusted partners.

"An investment in data liquidity within organizations will drive new applications," Mr. Arneman says. "Data liquidity includes not only technology but the cultural understanding of data sharing and the related legal and privacy considerations required to use it. From a technological perspective, systems enabling data collaboration, including the delivery, development and sharing of new ways of looking at data, will create an iterative process of creating value can be seeded."

Global Trends

According to Kevin Lai, director of biomedical sciences, Singapore Economic Development Board, to better access emerging markets in the Asia-Pacific region, life-sciences companies have to relook at global operational structures across R&D, manufacturing, and commercial.

"We believe that an integrated location with commercial, R&D, and manufacturing activities will allow key company decision makers and commercial leads to respond and adapt quickly to market needs through synergies created between critical elements within each function," he says. "For example, the commercial teams should channel market insights and demand sensing information more quickly to their supply chain and clinical development teams so that there is a shorter lag time.

"In light of the heightened importance of global compliance, we have seen a greater emphasis in recent years to develop strong regulatory competencies especially to help companies navigate in the fragmented and culturally diverse Asia market," he says. "Singapore is working closely with industry to build the right infrastructure and competencies to support this area. Case in point, Singapore is helping companies train regulatory affairs leadership teams and building regional audit specialist teams in Asia with good regional and local insights." PV

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