Robin Robinson

Executive INSIGHTS

CEOs, presidents, and executive management team members from across the industry — pharmaceutical, biotechnology, and service companies — discuss the most crucial factors driving change in the industry, as well as their strategies for meeting the challenges of business in the coming years.

JED BEITLER is *Chairman and CEO Worldwide* of **Sudler & Hennessey**, a global healthcare communications company. For more information, visit sudler.com.

Globalization and technology continue to grow as the most important factors affecting change in our industry. The increasing opportunities to reach, to teach, and to help more people from all parts of the planet; the increasing challenges associated with getting the right medicines in the right hands at the right price; and the increasing options to deliver messages to all professional and consumer audiences no matter where and no matter whether pixelated, in print, or in person are some of the many drivers of our evolving industry.

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JAY BOLLING is *President and CEO* of **Roska Healthcare Advertising**, a full-service advertising agency with expertise in engaging prospects through communications that integrate data and insight-driven marketing and advertising solutions. For more information, visit roskahealthcare.com.

Pharma's role of providing clinical value just isn't enough anymore. As pharma's customers are experiencing increasing demands from the government, they're looking for — and demanding — additional resources, support, and services that can help them increase patient satisfaction, health outcomes, medication adherence, and practice efficiencies. Healthcare professionals, payers, hospitals, ACOs, and other stakeholders are asking for greater value from pharma, and these requests are changing the dynamics of the life-sciences industry and redefining these stakeholder relationships.

In a world of me-too products and restricted formulary access, pharma must think beyond its traditional R&D deliverables in 2012 to provide a different type of value that it never has before.

Increasing profitability has been and continues to be the primary objective for any company. We are starting to see pharma throw off the tried and true and embrace innovative communications strategies that answer critical questions such as how to focus R&D efforts on the greatest areas of market need; maximize clinical trial results that truly differentiate products; minimize windshield time for sales representatives; reach more customers with the least amount of marketing investment; and better understand target audiences and what influences their decisions.

To achieve these objectives, companies will restructure their clinical, marketing, and sales strategies to include greater use of targeted drug therapy and diagnostic collaboration; payer partnerships; digital technology; nonpersonal promotion; influence mapping; and pharmacoeconomic analyses.

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DAVID DE GRAAF is *President and CEO* of **Selventa**, a personalized healthcare company that analyzes molecular patient data, accelerates the development process, and clarifies decisions on therapeutics and diagnostics for pharmaceutical and biotechnology partners. For more information, visit selventa.com.

The fundamental issue for the life-sciences industry is to turn from a drug-focused culture to a patient benefit-oriented culture. We have developed an economic model driven by drug sales, even if patients don't benefit or are adversely affected. The development of a new economic model of integrated and individualized prevention, support, and treatment needs to emerge from the current diseconomic chaos. We are where mainframe computers were in the 1980s. The new healthcare industry needs to diversify, find smaller, better-defined markets, and lead by innovation. This all starts with a deep understanding of molecular disease in individual patients. I foresee a much bigger emphasis on patient data and a deep need for the identification of individual and combinations of molecular disease drivers in each patient, giving us the ability to manage disease over its lifetime from a molecular perspective. Ultimately, this will lead to therapeutic approaches led by diagnostics, rather than drugs. These therapeutic diagnostics will determine whether or not to treat, which drugs in the formulary can or should be given, and aid in the identification of potential adverse events.

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ROBERT S. EPSTEIN, M.D., is *President* of **United BioSource Corp.**, a global scientific and medical affairs organization that partners with life-sciences companies to develop and commercialize their products. For more information, visit unitedbiosource.com.

The life-sciences industry is facing an exciting but challenging time. There are many factors that are accelerating and decelerating drug development and distribution in ways that we could not have imagined until now. The current situation in the financial markets has slowed new entrants and investments in healthcare. And heightened regulatory oversight has us sensitized to making sure the investments that are made pay off. However, new technologies are creating an environment of speed and affordability in discovering the molecular pathways of disease. The time from discovery to commercialization has shortened significantly. And the unabated growth in emerging markets creates a compelling reason to continue innovating.

For 2012, I believe the most important business objective UBC shares with its clients is to develop and implement custom evidenced-based strategies to ensure commercial success. We are leveraging our longitudinal prescription patient databases to analyze real-world issues and translate them into opportunities that are meaningful to client and payers.

We are intellectually engaging much earlier in biopharmaceutical development by convening multi-disciplinary client teams in late Phase I and using our global employees with cross-functional expertise to stress-test a client's novel product profile and future plans. This approach provides earlier identification of the subset of patients who might benefit best or have the lowest safety concerns, while building a plan for accumulating the evidence required by payers as stakeholders into the process. This has the potential to both make a new product better in terms of the totality of evidence of benefit or risk, but also more likely to penetrate the marketplace quicker since the payer stakeholder perceptions are addressed alongside those of the regulator. Likewise, we are leveraging disruptive technologies to capture investigational patient data, such as using mobile and smartphone apps and launching digital and Web-based methods to provide expanded scale, increased efficiencies, and greater accuracy of a global research program while containing costs.

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OLIVER FETZER, PH.D., is *President and CEO* of **Cerulean Pharma Inc.**, a clinical-stage company specializing in the design and development of nanopharmaceuticals. For more information, visit ceruleanrx.com.

Patent expirations of major drugs are affecting virtually every large pharmaceutical company and pipelines are not deep enough to replace future lost revenue.

Personalized medicines will continue to prove highly challenging and will not come close to replacing the future lost revenues. Many seem to overlook that the fragmentation of treatments due to personalized medicines will require substantial investments in the way clinical trials are conducted, companion diagnostics are developed, and physicians treat their patients. Effectively using the exponentially growing disease understanding requires a new approach in the way drug discovery and development are conducted.

The most important objective is to identify and successfully advance differentiated drug candidates to help patients. While it is clear that the industry has not been able to spend its way out of the pipeline crisis, new models have to prove themselves to create value more cost-effectively.

For Cerulean, our focus in the coming year is to generate clinically differentiated data in several serious solid tumor indications for our lead compound CRLX101, while proving that our nanopharmaceutical platform can target tumors with a wide range of molecules, including oligonucleotides such as RNA.

Companies need to focus early on highly differentiated efficacy and safety advantages over existing therapies in the relevant preclinical models. This needs to be followed by clinical trial strategies that effectively test hypotheses and allow solid going forward decisions. It requires extensive cross-functional integration in preclinical and early clinical development, which an experienced and focused team in a small biotech can take advantage of. While a large pharmaceutical company often has more expertise, the effective integration of that expertise has proven very challenging.

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JOHN GARGIULO is *President and CEO* of **Daiichi Sankyo Inc.**, the U.S. subsidiary of Daiichi Sankyo Co., Ltd., a global pharmaceutical company, dedicated to the creation and supply of innovative pharmaceutical products to address the diversified, unmet medical needs of patients in both mature and emerging markets. For more information, visit dsi.com.

Our overall goal is to build a best-in-class portfolio, with several first-in-class products emerging from our internal R&D, as well as strategic alliances with partners such as ArQule and Seattle Genetics and the acquisitions of the proven discovery and research platforms of U3 and Plexxikon. We now expect to see our portfolio expand and mature to build a sustainable business.

Our recent acquisition of Plexxikon accelerates our entry into the oncology market and provides us with our first opportunity to enter the U.S. cancer market. This important milestone strengthens our pipeline, and enables us to achieve our mid- and long-term business objectives of providing world-class, innovative pharmaceuticals in core areas of unmet medical need.

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MATT GIEGERICH is *Chairman and CEO* of **Ogilvy CommonHealth Worldwide**, Ogilvy CommonHealth Worldwide, part of the Ogilvy & Mather network

and a WPP company, is one of the largest healthcare communication networks with 65 offices across 36 countries. For more information, visit ogilvychww.com.

The most important objectives for Ogilvy CommonHealth Worldwide are to outpace the speed of change in the marketplace by focusing on better insights, ideas, innovation, and integration.

Achieving this objective will require a deft blending of traditional skills, new approaches, and new disciplines.

Rising to the fore will be global/regional brand perspectives, agnostic communications channel planning, digital and CRM-oriented solutions, and data and analytic feedback loops. Customer value will be the most important metric on all fronts.

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JANE HOLLINGSWORTH is *CEO* of *NuPathe Inc.*, a specialty pharmaceutical company focused on the development and commercialization of branded therapeutics for diseases of the central nervous system. For more information, visit nupathe.com.

Virtually all companies face greater regulatory uncertainty, longer timelines, and a rapidly evolving reimbursement environment. Emerging companies are tasked with meeting these demands while simultaneously navigating the increasingly choppy capital markets. For companies large and small, this challenging environment demands smart innovation, developing treatments that truly meets patient needs and doing so in the most creative, effective way possible. Figuring out the best business models for today's environment, as opposed to doing things the way we always have, is the key to successfully building new companies and developing new treatments for patients.

The most important business objective for NuPathe in 2012 is fairly straightforward. We hope to have our lead candidate, NP101, approved by FDA as the first single-use, transdermal sumatriptan patch for the treatment of migraine.

In my opinion, the numerous challenges facing the life-sciences industry should be seen as an opportunity to think differently and simplify one's approach to pharmaceutical development. At NuPathe, our motto is: serve the patients and sales will follow. For us, patients are the core audience and drive our development and commercialization strategy. The most important business objective for the life-sciences industry is to continue to innovate and bring new treatments to underserved patients in the most efficient, effective way possible. There are numerous obstacles to achieving success in this industry. Never losing our focus on patient needs is critical to overcoming these obstacles.

RJ LEWIS is *President and CEO* of **eHealthcare Solutions**, a solutions-focused advertising network specializing in the digital healthcare marketplace and providing access to the healthcare professional and consumer health audiences. For more information, visit e-healthcaresolutions.com.

As always, the political environment is an X factor. Out-of-control government debt driven by excessive entitlement programs puts a big target on the backs of the entire healthcare industry. As long as healthcare remains such a significant portion of GDP and government expenditure, pressures that lead towards trends like managed care and accountable care will only continue. The key is to evolve in a manner that is beneficial to society and become part of the solution, not just another layer on the problem.

We need to get back to the core of R&D and develop good quality innovative products that cure disease and improve patients' lives. Everyone needs to be part of the solution in making healthcare affordable, which includes educating and supporting preventive care, a good diet, exercise, and nutrition.

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FRANCOIS NADER, M.D., is *President and CEO* of **NPS Pharmaceuticals Inc.**, a specialty pharmaceutical company developing innovative therapeutics for rare gastrointestinal and endocrine disorders. For more information, visit npsp.com.

Companies will have to monitor and manage the impact of healthcare reform. Those companies that can clearly demonstrate the value of their products will do best. For many emerging companies, there are macroeconomic implications on the sector that have resulted in increased risk aversion among investors. This challenging environment puts pressure on companies' valuations and presents challenges to those needing financing.

The continued loss of key blockbuster products to generics mandates that companies continue to look for ways to grow, maximize, or diversify the potential of their pipelines. Companies will have to continue addressing payers' lower appetite to reimburse perceived expensive drugs. This reality underlines the critical importance of a solid cost-effectiveness value characterization. The unpredictability of the regulatory process and outcome, coupled with a lower benefit/risk tolerance, makes an evolving strategic regulatory approach essential.

Companies have need to keep close tabs on the implementation of healthcare reform and the current review by the Supreme Court, and continue working to build measurable value into their offerings.

The industry is directly impacted by the general state of the economy and the public perception and needs to shy away from self-centric positions that might secure short-term wins but long-term losses.

Emerging companies have to be ready to strengthen their balance sheet, when they can and when they don't need to rather than being tempted to

time the market. Additionally, focusing on the core business might free up some critical capital.

Generics are an important component of the current and future landscape and have to be dealt with as such. The industry ought to be creative, as some companies have been already, in integrating generics into their strategic process.

Characterizing and communicating the value of our products through solid health economics and outcomes research is becoming of paramount importance to pre-empt a backlash from payers — public and private — such as a negative NICE or PMPRB reimbursement recommendation.

Innovation will not survive without private funding, and private funding will continue to dry out given the unpredictability of the regulatory process. On the flip side, regulators have to be in a position to play their role with total scientific objectivity and integrity. There is no absolutely safe drug. The benefit/risk ratio has to always be determined with the patients in mind, not out of fear or greed.

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JAMES T. OGLE is *CEO* of **INC Research**, a therapeutically focused clinical research organization with a high-performance reputation for conducting global clinical development programs of the highest integrity. For more information, visit increasearch.com or follow at @inc_research.

Innovation — on many levels — will be the focus for life-sciences companies in 2012. The cost-cutting trend of recent years will be replaced by more innovative and out-of-the-box approaches to bring drugs and therapies to market while still growing shareholder value. For instance, instead of focusing solely on reducing margins for suppliers and outsourcers, biopharmaceutical companies will be forming more alliances with CROs where both parties can work toward taking costs out of the business.

Once biopharms and CROs establish mutually beneficial incentives and risk-sharing paradigms, we will see innovation not only with new drug development techniques, but also with new ways to reduce overall costs.

Drivers of change for 2012 include evolving alliance partnership models between drug developers and outsourcers that are simultaneously taking costs out of the process and spawning innovation in clinical development; a new wave of pharma investors that see opportunities in the compounds that the biopharmaceutical companies simply don't have the resources to develop internally, primarily due to financial pressures. These nontraditional funding sources will essentially form a new market segment, which can be considered a type of micropharma company because they will need to partner with CROs and other outsourcers to develop these compounds, as well as manage risk through diverse portfolios.

We have termed these arrangements networked drug development alliances, which include the asset holder, market, and operations experts and investors typically providing specific expertise in the therapeutic area being developed.

A new wave of innovation, and therefore competition, from emerging regions will be a market driver. Asia, for example, has growing and aging populations that are demanding access to the latest drugs. Native companies will be entering the clinical development market, which will crack open the monopoly held by Western countries.

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STUART W. PELTZ, PH.D., *President and CEO* of **PTC Therapeutics Inc.**, a biopharmaceutical company focused on the discovery, development, and commercialization of orally administered small-molecule drugs that target post-transcriptional control processes. For more information, visit ptcbio.com.

An important objective for the life-sciences industry is to maintain a commitment to pursue scientific innovations that matter by developing therapeutics for patients who have few or no treatment options. Our primary objective at PTC is to discover and develop novel medicines that we believe will make a significant improvement in patients' lives. Our goal is to identify first-in-class, first-in-mechanism drugs to treat such diseases. We do not aspire to incrementalism — the development of marginal improvements to existing therapies. We do not believe that this will sustain our industry. Companies that succeed in developing breakthrough treatments which address the underlying cause of a disease will become the industry leaders.

It is important to identify the areas of fundamental need that are not being addressed with current therapies, and to identify indications that have few or no treatment options, then to determine whether the unique insight can help address this particular patient need. The insight may be a new biological pathway, target, chemistry, or a clinical endpoint. It is important to then create and execute a sound development plan. It is important to note that entering new disease areas usually requires an understanding of the disease and its natural history. It may also be necessary to develop new clinical endpoints that have not been previously used in the chosen indication.

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ADELENE PERKINS is *President and CEO* of **Infinity Pharmaceuticals**, a company dedicated to discovering, developing, and delivering to patients best-in-class medicines for difficult-to-treat diseases. For more information, visit infi.com.

The promise of personalized medicine is finally at our fingertips, but not yet firmly in our grasp. While we have made great strides in being able to efficiently and cost-effectively integrate molecular and genetic characterizations of patients and their disease into drug development, we are confronted with many complex challenges that we must address to realize the true potential of this new era of medicine. Targeted drugs that provide a truly meaningful benefit for patients are essential to delivering cost-effective solutions to payers and justifying the value-based pricing necessary to

fund ongoing research and generate returns for investors. Access to the significant amounts of capital needed for drug discovery will be dependent on our success in developing drugs that really work, which will require that we better define specific patient populations through personalized medicine initiatives.

A related factor affecting our industry is short-term capital market pressure driving changes often at odds with developing innovative drugs. Limited access to capital is creating pressure to consolidate as big pharma is faced with patent expiries and the need to cut costs and biotechs struggle to find funding. However, consolidation can make adoption and integration of new technologies more challenging because of the focus on numbers instead of the teams needed to process information and develop strong hypotheses to be tested in the clinic. I believe this is best accomplished in smaller, focused organizations in which discovery, development, informatics, regulatory, and commercial people interact on a daily basis.

To restore society's confidence in our industry, we need to prove that we can develop drugs that meaningfully improve patients' lives and that we can deliver those drugs cost-effectively. Expensive drugs that provide a marginal benefit in a very small fraction of patients will — and should — no longer be tolerated.

Infinity's 2012 objectives are aligned with those of the industry. We need to show that our drugs provide a significant patient benefit, and we have several trials under way to achieve this objective. In diseases for which there are no effective therapeutics such as pancreatic cancer, chondrosarcoma, myelofibrosis, and non-small cell lung cancer, we need to show that our drugs work to meaningfully enhance the quality and extend the length of patients' lives. We have Phase II trials under way in each of these indications and are committed to revealing the potential of our pipeline from the second half of 2012 and during 2013.

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DR. ARIS PERSIDIS is *President* of **Biovista**, a privately held biotechnology company that finds novel uses for existing drugs and profiles their side effects using their mechanisms of action. For more information, visit biovista.com.

On the business side, cost of development, regulation, the patent cliff, emerging markets, and generics moving toward IP generation are driving major changes. In particular, the cost of development together with worldwide payer organization postures make current models unsustainable. This is driving pharma to find more efficient ways to develop drugs and to maximize the value of their existing portfolios. On the technology side, newly drug-able targets and advances in insight generation and knowledge management are driving changes in the direction of R&D.

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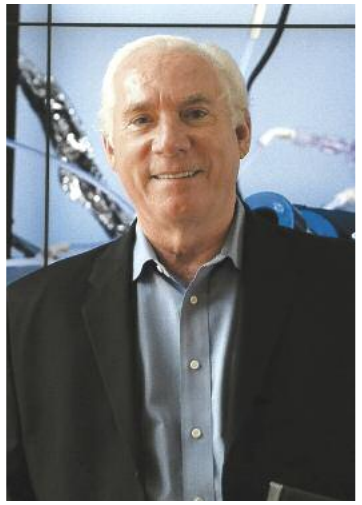
JOHN RODENRYS is *CEO* of **InflammaGen Therapeutics**, a biotech company that has developed a new treatment, assay, and lavage to treat and diagnose multiple organ dysfunction syndrome (MODS), formally known as multi-organ failure. For more information, visit igenrx.com.

A few factors that are driving change in the industry are the lack of new



products able to replace the revenue stream from the significant number of medications losing patent protection and the challenge of conducting research outside pharma's comfort zone. This has had a dramatic, negative effect on market cap and stock prices of companies in the industry.

Finding a solution to treat or prevent septic shock is a good example of this. There are currently more than 200 clinical trials listed on clinical trials.gov regarding septic shock. Even though current research strategies have been shown not to be effective, these trials and many investigators continue to focus on treating the symptoms of septic shock with the hope that somehow they will have a different outcome. Because of the need to change, we have developed a collaboration with UCSD to solve these challenges.

This changes the paradigm in which disease sets are considered and research conducted and coordinated. This partnership has shown to be a solution to the above mentioned challenges, including costs. The America Invents Act also changes the U.S. patent process, which will lead to significant changes in the way research-based patents will be filed.

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ANGUS RUSSELL is *CEO* of **Shire**, a specialty biopharmaceutical company. For more information, visit shire.com.

The global recession continues to affect all organizations, including healthcare and life sciences. In the midst of this economic tumult, healthcare products and services are under ever-increasing payer scrutiny as they determine what to reimburse and how to prioritize the health needs of their citizens. Shire provides patients with specialist, differentiated and innovative medicines and treatments for chronic, symptomatic conditions and we recognize the need to provide tangible benefits to patients, carer givers, and their families while delivering value to physicians, policymakers, payers, and more broadly, to society. The industry is experiencing immense change and for companies to survive and thrive they must focus on delivering meaningful value to their multiple stakeholders.

To succeed in the current challenging and ever-changing economic and regulatory environment, pharma companies must develop products that demonstrate tangible value to the entire stakeholder spectrum beginning, of course, with patients but also including regulators, policymakers, payers, and physicians.

The success of a company will be based on the ability to innovate and target specific unmet needs and to ensure that the economic justification for a newly developed treatment is built in from the earliest stage of development. This will mean engaging early on in the process with policy-makers, payers and regulators to ensure that societal healthcare needs are mutually understood and that R&D investment is prioritized accordingly.

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DR. SEVERIN SCHWAN is *CEO* of the **Roche Group**, which focuses on developing medicines and diagnostics that will help patients live longer, better lives. For more information, visit roche.com.

We will continue to better understand diseases and target their genetic specificities. Demand for innovative medicines and diagnostics will be tested against ongoing pressures on public healthcare budgets. Society's resources will be allocated to those solutions that provide true medical benefit for the individual patient. To this end, patient stratification before treatment by means of molecular diagnostic technologies will get increasingly important.

In 2012 and beyond, our main goals remain to develop and market novel medicines and diagnostic tests for patients in need.

We continue to leverage our combined strengths in pharmaceuticals and diagnostics and proven expertise in molecular biology to benefit from the industry trend towards personalized healthcare. At the same time we are constantly working on productivity improvements across the entire organization.

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RICHARD THOMAS is *Chief Information Officer* of **Quintiles**, a fully integrated biopharmaceutical services company offering clinical, commercial, consulting, and capital solutions worldwide. For more information, visit quintiles.com.

Inside pharma, IT departments face tumultuous challenges that include deep cost-cutting, a constant stream of regulatory audits, and numerous legacy systems with process and data silos that constrain productivity. Cloud computing offers a unique but effective way to address this. At Quintiles, we have been diligently assembling our entire portfolio of clinical applications and patented technologies that we use internally, integrating and then transitioning them into our private cloud service. From there, they are available to our customers on just about any device with an Internet connection; laptops, smartphones, iPads, and more.

These systems, by their nature, are complex and take time for users to adapt to. Combined with rapidly a changing technology landscape, it is abundantly clear that IT groups cannot exist in the vacuum of being all-knowledgeable when it comes to business technology innovation.

Success requires a true partnership between business groups, suppliers, and internal IT personnel who in turn has to have a deep understanding of the operations and needs of the ultimate customer. The best news is that in many ways this technology revolution has only just begun.

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LEE VALENTA is *President* of **OptumInsight Life Sciences**, which specializes in technology services, information, analytics, business services, and consulting. For more information, visit optum.com.

Life-sciences companies are under mounting pressure to deliver and succeed in an ever-changing and increasingly competitive global economic and regulatory landscape. Therefore, as we look at next year and beyond, the life-sciences industry faces a number of significant global challenges, including: regulatory globalization and convergence; growing importance of patient insights based on real-world evidence; mounting regulatory scrutiny of drug and device efficacy as well as risk management and safety; market access issues in both established and emerging markets; and health economics, including the importance of measurable health benefits from investment, and the increasing use of value-based pricing models.

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JAMES C. WALKER is *CEO and Chairman* of **Octagon Research Solutions Inc.**, a provider of software and services to the life-sciences industry. For more information, visit octagonresearch.com.

Standards are the most important driver of not just change, but industry-shaping transformation. Standards will reshape how we think about, collect, and manage information related to drugs and devices — consider financial services and how standards drive the coordination and information flow around the world.

Standards will shift our view of data collection and regulatory submission from discrete tasks to a holistic, synchronized process that collects and connects clinical data across the entire drug development continuum. This shift in processes will cause industry to move from a "point solution" model that automates individual tasks — IVRS, CTMS, EDC, etc. — to an optimal, synchronized model that shapes and connects how clinical data are consistently acquired, exchanged, submitted and archived, reaching from pre-IND to submission and beyond.

In short, standards are the catalyst for electronic transformation, process synchronization, and resource optimization. With the FDA embracing standards, we will begin to see the facilitation of industrywide adoption of a consistent framework to acquire, receive, and analyze study data. This improvement of processes will establish enhanced and refined data analysis capabilities, time-to-market gains, and cost efficiencies, ultimately benefiting the life-sciences innovation environment and global patient population. PV