



Past, Present, AND FUTURE

PharmaVOICE celebrates 15 years of trends with a look back at the market forces that have defined the industry and what's ahead as the healthcare ecosystem continues to be reinvented.

The world today is much different from when PharmaVOICE began publishing 15 years ago. In the United States, George W. Bush had just taken office, replacing Bill Clinton. Today, Jeb Bush and Hillary Clinton are running for president. Okay, so while some of the names in politics remain the same, the country and the world are very different. Our first issue had gone to press and we were putting the final touches on our second issue when the Twin Towers went down that fateful September 11th morning.

Several other major events punctuated the calendar during 2001, which have or continue to affect the industry:

- ▶ **IN 2001:** Pharmaceutical companies agree to sell AIDS drugs at cost in Africa, a discount of up to 90% to help the fight against AIDS.
- ▶ **TODAY:** New HIV infections have fallen by 35% since 2000 and AIDS-related deaths have fallen by 42% since the peak in 2004.
- ▶ **IN 2001:** The world's first contraceptive patch Ortho Evra, from Janssen, receives market approval.
- ▶ **TODAY:** The Ortho Evra patch, which was made available on U.S. pharmacy shelves in 2002, was discontinued in late 2015 "due to a business decision," according to information on the FDA website. A statement from the company confirms that "Janssen Pharmaceuticals has decided to discontinue its birth control patch Ortho Evra (norelgestromin/ethinyl estradiol transdermal system) in the United States." A generic version of the contraceptive patch is now available.
- ▶ **IN 2001:** The human genome sequence and the preliminary analysis result were revealed on February 12 jointly by scientists from China, Japan, Germany, France, Britain, and the United States, and Celera Genomics, a U.S. company. The human genome was proved to contain some 30,000 to

40,000 genes consisting of 3.2 billion alkali base pairs. This was a major step in exploring the mystery inside the human being. It was estimated that the work of mapping the entire human genome would be finished by the year 2003. In 2001, reports estimated that the cost of sequencing was just under \$10,000.

- ▶ **TODAY:** Through 23andMe, anyone can get a personalized analysis of their DNA and discover their ancestral origins and trace their lineage for less than \$200.
- ▶ **IN 2001:** The most serious economic slowdown in 20 years occurred in most areas of the world. The U.S. economy went into a recession starting in March; affected by the U.S. economic fallout, the 15-member European Union underwent a sharp economic contraction; the Japanese economy experienced a further deterioration; the Asian economy, which was on recovery from the 1996 financial crisis, also slowed its pace of growth; and the Latin American economy plunged into difficulty, with political disturbance breaking out in Argentina owing to the country's economic crisis at the end of the year. The September 11 attacks not only dealt a blow to the U.S. economy, but also severely affected the economies in other parts of the world. The International Monetary Fund estimated that the world economy would grow by only 2.4% that year, 2.3 percentage points lower than the previous year. (Editor's Note: Great time to start a new publication, right?)
- ▶ **TODAY:** The global economy is in a holding pattern in which positive and negative forces offset each other, at least for the immediate future. This characterization of the global economy is unlikely to change in the next 12 to 24 months. After adjusting for China's overstated official growth rate, analysts project a very modest improvement in the growth rate for the global economy to 2.8% in 2016, up from 2.5% in 2015.



For this month's cover story, we asked industry experts from all sectors — from the clinic to commercialization — to provide us with the biggest change they've seen in the past 15 years and what they see on the horizon. By all accounts the biggest trend has been the move to a more patient-centric healthcare model, closely followed by the impact that technology is having on all areas of the life sciences as well as changing business models. Industry leaders also discuss shifts in the cancer category, factors impacting clinical development, global market influences, healthcare delivery, M&A, and other trends.

We hope you enjoy these reflections and projections on the influences shaping the life-sciences industry.

When we began publishing PharmaVOICE in 2001 and using the term life sciences as part of our message and vision, this holistic approach to covering the industry was a nascent concept. Then, as now, we believe life sciences constitutes the companies, organizations, and people involved in moving a pharmaceutical, biopharma, biotechnology, device, product, tool, or service along the continuum of care.

We thank the thousands of industry experts who have raised their voices on the important trends of the past, today, and tomorrow and for helping to move the life-sciences industry forward.

Today, according to Deloitte, aging populations, chronic/lifestyle diseases, emerg-

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2016: A Shake Up Year

As the industry copes with the continued influx of the newly insured, the rising burden of medical costs, and a host of new technologies for patients and doctors alike, startups and entrenched companies will look for new ways to reach customers. Patients, meanwhile, will be looking for better methods to manage their medical expenses and their health, according to a new report from PwC. Also, get ready for healthcare to get political.

DRUG PRICING SOLUTIONS.

Concerns over drug prices have reached fever pitch in the U.S. Price increases for branded drugs have outpaced inflation every year since 2006. Even generics prices are inching up, gaining 9% on average since 2014.

One approach that pharma companies may try is an alternative financing model, which spreads out payments for expensive drugs in order to make the cost easier to handle. More than half of consumers polled by PwC said they would be willing to pay for a pricey drug over time rather than bear the full brunt all at once.

There will also likely be more outcomes-based reimbursement agreements struck in 2016. These agreements between pharmaceutical companies and insurers or

health systems link payment for a drug to the health outcome rather than simple volume of product used.

MERGER MANIA WILL CONTINUE.

2015 was a year of massive mergers, from Anthem's \$48.4 billion offer for Cigna to Pfizer's jaw-dropping \$160 billion deal for Allergan. That trend will likely continue in 2016, especially since many of the deals will still be facing regulatory scrutiny over the coming months.

Consolidation will likely beget more consolidation, as smaller companies look to boost their negotiating power when competing with new, larger rivals. As healthcare gets more tech savvy, insurers, health systems, and pharmaceutical companies will be looking for better data analytics and new products to complement existing services.

GET CARE WHEN AND WHERE IT'S CONVENIENT.

Health apps came into their own in 2015 with the telemedicine app Teladoc, making its debut on the public markets. Teladoc's membership has boomed to 8.1 million and continues to expand.

More people are adopting digital health apps to manage their care when and where they want it. Patient adoption of health-related apps nearly doubled over the last two years. About 32% of consumers had at least one health app

on their phones in 2015, up from 16% in 2013, according to the PwC report. Connected devices that go well beyond a fitness tracker — think EKG monitors, glucose trackers, connected pacemakers — will spur greater adoption of apps that help patients better monitor their health. These apps will be especially valuable for sharing information directly with doctors for controlling chronic conditions.

CYBERSECURITY IS GOING TO BE TOP OF MIND.

With more using digital health apps and services, privacy and cybersecurity will be top of mind for both consumers and providers. Insurers have already had a rough go of it recently, facing hacks that have affected hundreds of millions of customers in total. Almost 40% of customers polled by PwC said they would abandon or reconsider using a health organization if it were hacked.

IT'S GOING TO GET POLITICAL.

The election season is well under way, and there's already been a number of healthcare proposals from candidates on both sides of the aisle. With the high-profile tax inversion mergers by pharmaceutical companies, rising medical costs, and high drug prices, healthcare will remain a key issue in 2016.

Source: Fortune's Laura Lorenzetti and PwC Health Research Institute's directors Benjamin Isgur and Trine Tsouderos

ing-market expansion, and treatment and technology advances are expected to spur life-sciences sector growth. But, efforts by governments, healthcare providers, and health plans to reduce costs, improve outcomes, and demonstrate value are dramatically altering the healthcare demand and delivery landscape. It is becoming increasingly evident that the global life-sciences sector is operating in an era of significant transformation.

According to Deloitte, the extended nature of life-sciences product development mandates that sector stakeholders adopt a long-term approach to strategic planning, portfolio management, and market expansion. However, organizations must also prepare for and react to near-term challenges and opportunities. Four major trends are expected to capture the sector's attention in 2015: searching for innovation and growth; changing regulatory

and risk environment; preserving and building shareholder value; and preparing for the next wave. The resulting challenges and opportunities can be both global and market-specific.

Adapting business models to account for innovations such as personalized medicine,

applying technology innovation to healthcare delivery, talent strategies, and continued expansion and presence in emerging markets will further present challenges and opportunities for companies as they adjust to and meet the needs of this continually changing sector.

► Patient Centricity

Since the term patient centricity came into vogue several years ago, it has become so overused that its meaning has become multi-fold — covering everything from patient care to how to best deliver healthcare.

But no matter how you define patient centricity, the shift is definitely on. From big pharma and biotech companies to the thousands of companies that make up the life-sciences ecosystem everybody is getting personal.

As Alex Gorsky, chairman and CEO of Johnson & Johnson, says: "Healthcare is personal."

The industry's focus on the patient is being fueled by the new healthcare economy and the delivery of customer-centered care. PwC defines the new health economy as one in which "patients" will be "consumers" first, with both the freedom and responsibility that come with making more decisions and spending their own money, and they will demand a contin-



uum of well-being, rewarding the trusted advisers that help achieve that goal.



CHRISTI SHAW
US Country Head,
President, Novartis Corp.
President, Novartis
Pharmaceuticals Corp.

The role patients are now playing in healthcare — their access to information and desire for choice and shared decision-making — is quite remarkable. At Novartis, we are engaging with patients in many new ways and defining innovation much more broadly — not just in terms of improving products but also incorporating patient input into study protocols and developing new tools to help them better manage their disease. We're also working with patients to navigate our complex healthcare environment and developing value-based solutions that can help them access innovation, all with the goal of achieving better health outcomes.



CRAIG BAKER
Executive VP, Noble

The dramatic growth in biologics has led to an increase in the number of patients who self-manage complex treatments using self-injection devices. These unsupervised treatment programs are difficult for patients to learn and cause anxiety, leading to a greater risk of noncompliance and patient errors. To solve this issue, the biologics industry has placed an emphasis on patient-centricity and human factors, which focus on learning more about patients, both behaviorally and cognitively. This new focus has proven beneficial, resulting in better devices, improved patient on-boarding programs that include training technology, and an increase in loyalty and compliance among patients.



DREW DESJARDINS
Executive VP, Chief
Strategy Officer, Dudnyk

The manner in which we interact with patients who suffer from a rare disease has dramatically changed. The widespread adoption of digital and social media and changes to the healthcare system to facilitate access to medications have created opportunities to interact directly with patients. Hub services offer companies a means of ensuring medication access, patient educa-

tion, and developing one-to-one relationships with patients. These changes have enabled companies to encourage strong emotional bonds through patient-designed support programs, activities that foster brand loyalty, and better patient compliance. When launching an orphan drug today, you simply can't launch without the patient component.



MAGGIE HELMIG
Executive VP,
Global Brand Lead,
Ogilvy Healthworld

From my perspective, the most important change is the elevated voice of the patient. This new voice is reshaping how physicians and pharma companies do business. Patients are no longer passive players. As employers and insurers shifted costs to patients, they have become more discerning consumers. They have options and are now demanding better care. Online patient communities and patient advocacy organizations have provided a platform and a mandate for a new patient engagement model. Fifteen years ago, the healthcare industry had a very paternalistic view of patients; now the patient is at the center, as they should be.



CATHERINE SOHN,
PHARM.D.
Board Director and
Chairman, Nominating &
Governance Committee,
Neuralstem Inc.

Two transformational changes that have occurred over the past 15 years, that PharmaVOICE has covered so well, include: the reliance on external innovation, at small companies or universities, by large biotech and pharmaceutical companies, for discovery of new medicines and vaccines; and the engagement of patients and patient advocacy organizations in product development and commercialization of medicines. Both external innovation and "patients at the center" have transformed and accelerated bringing important new medicines to patients who are waiting, and this is the important mission that drives so many of us in the industry.



MIKE REA
CEO, IDEA Pharma

The emergence of design thinking has been a major trend. Wherever a company claims it is patient-centric, I hope that is what it means:

developing medicines that meet real needs — and importantly getting them to market in a way that means they get to real patients; designing development for market access as well as regulatory hurdles; and meeting purposeful, meaningful endpoints rather than lowest-common-denominator. In the past 15 years, the same time IDEA has been around, those companies that have understood design thinking have outperformed their counterparts. And they will do so for a long while yet.



MICHELLE MIDDLE, M.D.
Medical Advisor,
Synexus Clinical
Research SA

The life-sciences industry has moved from being self-focused to becoming truly patient-focused and taking a global view on health issues. We are now much more focused on developing the drugs that are needed globally, including patients with rare diseases. We are focused on finding innovative ways to be more efficient with our resources and have become much more focused on information sharing and collaboration.



NADER SADEK
Training and
Development Manager,
Impact Inc.

Over the past 15 years, the pharmaceutical industry has undergone a dramatic transformation, from just selling products to the concept of customer focus and relationship management by initiating partnership programs, providing highly customized messages to healthcare professionals, and acting as a real partner with stakeholders. At the same time, companies are incorporating numerous awareness programs and marketing activities directed for patients and the community so as to enhance disease area awareness aimed at having healthier communities and enhancing people's lives.



ELYSE RETTIG
Senior VP, Media,
Publicis Health Media

The tipping point for people proactively embracing health management — on all fronts — has arrived. Individuals are telling us exactly what they want to know, where they choose to engage, and in which formats. We have built our practice to develop tools and content that embraces those

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INTIMATE LOGISTICS

Biologics, clinical trial products and other complex medications in the global market have created demand for specialized handling. With needs ranging from -196°C to body temperature, specialty packaging and transport help keep products intact, while a worldwide network of over 140 offices deliver products to sites in time. Securing the supply chain to emerging markets takes an expert in global logistics. It takes efficient transport solutions. It takes AmerisourceBergen.



ItTakesAmerisourceBergen.com



personal moments of connection based on deep insights around healthcare conversations, crafting distinctive experiences across patients, caregivers, and HCPs. Within the media space, we are helping our clients and partners change their approach to one that designs integrated media moments.



LIZ KAY
Group Account Director,
LehmanMillet, a member
of Precision for Medicine

The confluence of the Affordable Care Act, advancing technology, and consumer-driven healthcare creates many opportunities to impact care for the better. We're focused on brands that are changing the standard of care. Tapping into the multitude of channels — many still revealing themselves — we look forward to drawing on every means and media to uproot the status quo and introduce these medical innovators to truly advance patient care.



STAN WOODLAND
CEO,
CMI/Compas

The shift to audience-centricity has heralded a welcome overall industry change; by thinking first of audience needs and interests, we've been able to better use emerging media, better innovate, better segment and target, better engage, and be true to the mission of creating better health outcomes. Tactically, it has let us usher in true game changers of technology, including social media marketing/monitoring and programmatic buying.



CHRISTINE ARMSTRONG
Managing Director,
Brand Experience,
Giant Creative/Strategy

The biggest transformation has been the change of in-house expertise we employ to support, ideate, and validate our creative strategies. No longer is it enough to bring a singular campaign into market based on traditional research. Now, well in advance of a creative brief, we are orchestrating in-depth research on the usage and consumption behaviors of our targets, evaluating the social sentiment of the landscape, and designing more dimensional creative strategies aligned to the behaviors of identified personas and delivered across numerous channels, platforms, and

touch points, all interrelated and measurable to understand better the systemic impact of our solutions.



JESSICA BRUEGEMAN
Senior VP, Health
Behavior Group,
MicroMass
Communications Inc.

As an agency specializing in behavior change, we have noticed a shift within pharma. Pharma is recognizing that behavioral science and health psychology can provide a better understanding of how to meet the needs of patients and physicians. Pharma sees that patients and physicians are people. They have barriers and challenges that affect their beliefs, behaviors, and how they make decisions about their health. That's why behavioral science approaches are gaining traction as a proven way to produce better health outcomes. We see pharma going beyond product messaging and working to find ways to leverage behavioral science at all stages of commercialization.



RICHIE BAVASSO
CEO, Rimedio Inc.

Perhaps the biggest change over the past 15 years has been that industry used to own its most effective channels to the customer. Now, its most effective channels cannot be controlled or bought. Secondly, the entire conversation between the industry and its customers has changed in terms of the subject matter, which has moved from promotional influence to customer-centric and value-based outcomes, and the channels, which have transitioned from largely live interactions to a multitude of digital channels. There is also much more noise and influence on industry's messaging as it traverses from the source to the customer.



GREGG FISHER
Managing Partner,
The Stem

In 15 years the biggest change in pharma marketing has been the shift from product-centric to customer-centric thinking. This shift, propelled by regulation, competition, and technology, has rewritten the rules of marketing: from brand-message push to health-outcome pull. Leading pharma companies today recognize they are increasingly in the health solutions business vs. product marketers. They know

their success requires an intimate understanding of the customer to design experiences that foster healthy outcomes during each step of the journey. We are several years into this customer-first transition. It is far from complete, but pharma marketing will never be the same.



TIM GARDE
Chief Innovation Leader,
Life Sciences,
LevLane Advertising/PR/
Interactive

The world has changed since 9/11, we know this. And in the life-sciences industry, it has been 15 years of what I call patient engagement and communication transformation — targeted technological advances that have provided for increased communications between healthcare professionals and their patients or family caregivers whether through mobile technological advances, including wearables, real-time adherence/compliance programs, search engine marketing or social media initiatives, informative educational videos on YouTube, or enrollment in CRM programs. Patients have become more aware and better educated on their disease states or illnesses and the focus is on the patient journey. The transformational era is now also better purposed to solve specific patient-related issues such as hospital readmissions, fraud and abuse, care coordination, and interpretation of PHR and EMR databases. The end game is, and has always been, to improve constant dialogue between HCPs and their patients or family caregivers to maximize health outcomes and increase the quality of life. We are just at the beginning. Now let's see what the next 15 years will bring. I can't wait.

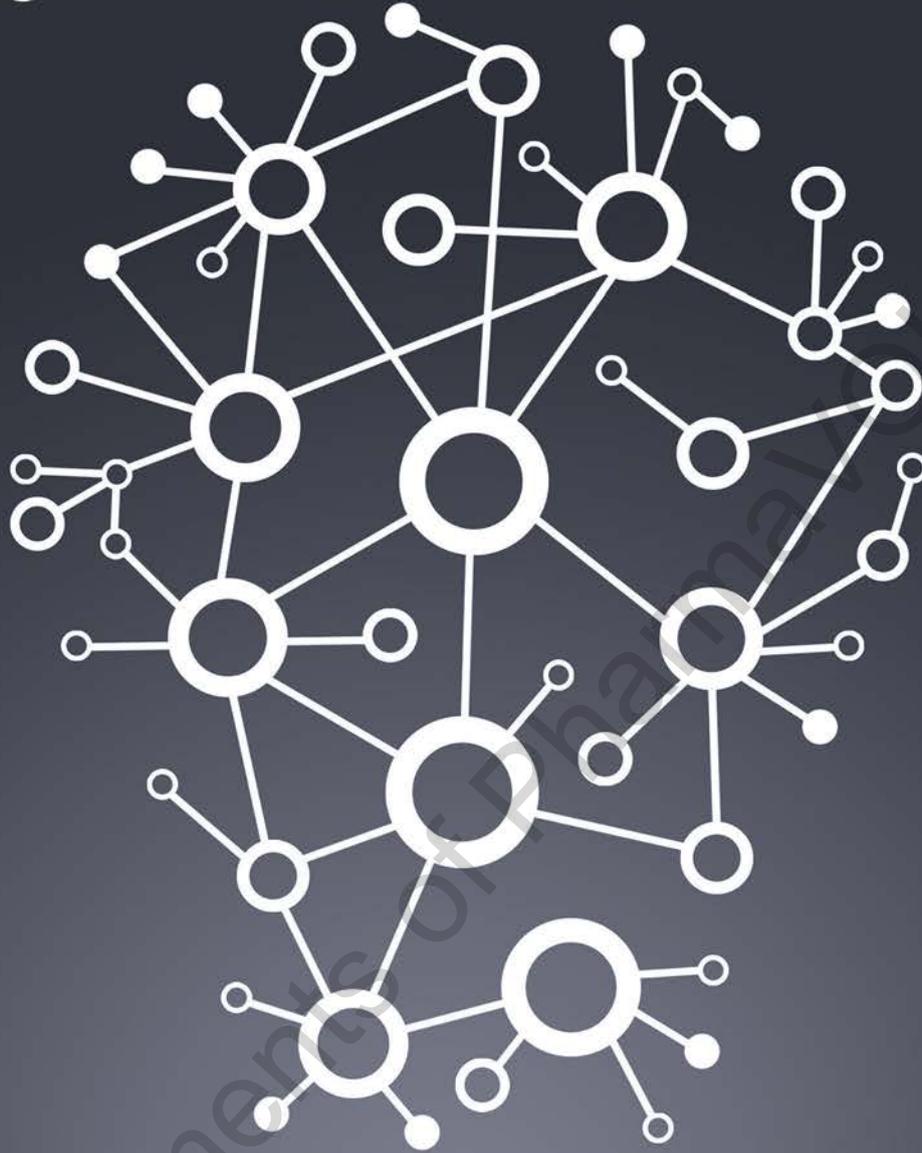


MARC SIROCKMAN
Executive VP and
General Manager,
Artcraft Health

The 15-year evolution of the patient-centric healthcare equation is undeniably a large change. However, while the patient continues to be at the center of our healthcare strategies, our perspective and expertise have equally expanded to address the needs of all stakeholders. This can be done through solutions that promote and maintain clear communication and understanding through engaging interactive omnichannel formats that simplify clinical data and analyses for healthcare providers, caregivers, and internal and external corporate pharma teams.

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Congratulations **PharmaVOICE**



www.hhealth.com

Huntsworth Health, the home of innovative agencies with exceptional talent, congratulates PharmaVOICE on its 15-year anniversary. Huntsworth Health and PharmaVOICE started life at the same time as innovative businesses that wanted to make a real difference. We both continue to strive for these lofty goals in a rapidly changing—but tremendously exciting—health care environment.



KRISTIN KELLER
Executive VP, Client Engagement, Discovery USA

The old-school dynamics of physician promotion and education have massively changed over the last decade, driven by the shift in industry focus to high-science specialties, physician expectations, and greater focus on scientific engagement. This has required a retooling of the definition of promotion vs. medical communication. We have watched this trend and have adapted to it by bringing together one integrated team, with one integrated strategic approach, to support all of a brand's needs — from promotion to education and peer-to-peer engagement. This approach enables us to flexibly adapt to the needs of our customers.



NEIL MATHESON
Global CEO, Huntsworth Health

The past 15 years have seen dramatic change in the way in which the healthcare industry communicates with stakeholders. This communication revolution has been driven by digital technology and the ability to engage audiences with credible, relevant, and emotional content in the right place, through the right channel, at the right time. The digital explosion has also empowered consumers and patients to become involved in decisions regarding their health and well-being and to seek the information they need to make informed decisions regarding their treatment options. The healthcare industry is now driven by quality of care as a key factor in the determination of true value — not just value to the patient but value to the healthcare system as a whole.



GREGORY BIRGFELD
Senior Director, Digital and Social Media, Pharmacyclics, an AbbVie Company

The voice of individual patients and the caregivers on social has never been as loud or as important; we can't not listen.

JAY BOLLING
CEO
PulseCX

Over the past 15 years, marketing/communi-



cations in the life-sciences industry has undergone significant change. In 2000, the BlackBerry was just introduced, clients were building their first websites, and DTC advertising was “the” new thing. Detailing and “advertising” to doctors — and now consumers — was our focus. We made sales aids (print) and journal ads. Now, 15 years later the marcom channel mix barely resembles its past. More than 50% of physicians restrict rep access, “feature/benefit selling” is dead, and customer experience marketing is at the core of everything we do. Brad Jakemen, president at PepsiCo, recently said “ad agency models are breaking” and “the phrase digital marketing should be dumped.” He suggested the phrase “advertising” should go away and stated the “global alignment agency” is now a dinosaur concept.”



JIM MCDONOUGH
VP, Marketing and Customer Advocacy, Frontline Medical Communications

In the past couple of decades, pharma has evolved from a salesforce-centric, mass market, bigger is better, primary care-oriented emphasis to a more narrowly focused, alliance-driven, biologics-centric, and specialty-directed industry. In the next 15 years, I hope the industry becomes even more patient-centric in its approach and is better able to communicate “value” to all their constituents.



BORIS KUSHKULEY, PH.D.
Executive VP, Multichannel Marketing and Consulting, Intouch Solutions

When I began in the industry more than 15 years ago, one-size-fits-all traditional advertising and a heavy reliance on the salesforce were ubiquitous. Today that's being replaced with smart, integrated multichannel campaigns. We are less focused on a hard sell, but instead anticipate customer needs and deliver value far beyond just communicating brand features and benefits. Pharma marketers are no longer looking for flashy creative campaigns; they expect their agencies to build intelligent, dynamic, personalized services that engage customers, build loyalty, and are measured and optimized in real time. Only organizations that were built digital-first are uniquely prepared for these new challenges.



MALCOLM BOHM
CEO, Liquid Grids

Salesforces have been cut. Rep access to HCPs has dropped dramatically. Conversely, the Internet has exploded and has led us to the era of prominence of the patients. Leveraging the patient as our best detail aid is the opportunity we must now embrace. This requires a whole new skill set away from traditional DTC and into digital communications and marketing. We saw this coming and continue to evolve our technology to further enable this digital revolution for pharma.

► Technology

When PharmaVOICE launched 15 years ago, Facebook was but a twinkle in Mark Zuckerberg's eye and the rest of the social media channels that are dominating our conversations today as they relate to online access to patients, physicians, consumers, and other stakeholders were also still on the drawing boards in living rooms around the country. These media, which started as consumer-based vehicles have morphed into powerful mechanisms for life-sciences companies for not only delivering communications, but understanding customers' perspectives on any number of topics. And while final guidelines for online or social media practices have yet to be officially sanctioned, not surprisingly pharma companies — for the most part — still look for solid footing from a regulatory standpoint. Despite continuing hesitation and the full embrace of

these vehicles, online is not only here to stay but growing more powerful every day.

Digital is taking the industry by storm as well. Most people have in their possession more computing power than NASA had to launch the first space capsule in the 1960s, and it fits in our hands. Our cell phones, and who really uses them for talking anyway, have the capabilities that were science fiction-oriented 15 years ago.

As part of the technology revolution, only superseded in the estimation of some experts by the industrial revolution of more than 250 years ago, in terms of a far-reaching impact has been the emergence of the concept of big data and all its associated analytics, segmentation, cloud-based service bells and whistles.

According to various sources, the idea of big data emerged in a 2001 research report

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by META Group (now Gartner) analyst Doug Laney, who defined data growth challenges and opportunities as being three-dimensional, i.e. increasing volume (amount of data), velocity (speed of data in and out), and variety (range of data types and sources).

This “3Vs” model continues to be used to describe big data. A dozen or so years later, Gartner updated its definition as follows: “Big data is high volume, high velocity, and/or high variety information assets that require new forms of processing to enable enhanced decision making, insight discovery and process optimization.”

Today, there is no corner of the life-sciences industry immune to the spotlight of technology to improve processes, reduce costs, and enhance efficiencies. From drug discovery to clinical trials to drug delivery to commercial practices, technology innovations will continue to push the industry into uncharted territory.

The software insights company Tableau reports that what’s really going to make big data go mainstream is the ability to connect not just with data scientists and technologists but business people. And absolutely one of the keys to that is visualization and being able to show people — not just tell people, not just show numbers, or even show charts — but to have those charts and graphs and visualizations come alive.

Tableau also reports that while it is still in its early days, the data from devices in the Internet of Things will become one of the “killer apps” for the cloud and a driver of petabyte scale data explosion. For this reason, they see leading cloud and data companies such as Google, Amazon Web Services, and Microsoft bringing Internet of Things services to life where the data can move seamlessly to their cloud based analytics engines.

And nontraditional companies, such as Google — and its associated alphabet of innovation hub departments — Microsoft, Amazon, GE are changing the life-sciences landscape as they enter into uber-tech deals with the J&Js, Novartis, and Pfizers of our world.



GRETCHEN DIECK, PH.D.
VP, Signal Detection & Surveillance, UBC

It’s all about technology. Increased availability of automated tools and data accessibility allow for more efficient signal detection and risk assessment. These changes have allowed pharma to become more proactive in identifying and evaluating safety issues, in refining signals, in comparing risks across different populations and regions,

and in some instances in evaluating whether safety measures have resulted in reduced risk.



STEVE ROSENBERG
Senior VP and General Manager, Oracle Health Sciences

The emergence of new sources of data has had a major impact on the industry. Since scientists unveiled the sequencing for the human genome 15 years ago, new data sources, such as social media — along with genotypic and phenotypic data — provide real-time perspectives on individuals and populations. This information enables organizations to monitor drug effects more effectively, support adaptive study designs, improve the overall probability of technical success, reduce trial costs, and help identify targeted therapies for the right patients. We continue to advance our ability to collect, normalize, share, process, and analyze data — down to the molecular level — from many disparate sources to improve clinical trials and the resulting drugs and therapies. There are several exciting initiatives in the area of precision medicine, delivering data-driven intelligence solutions and thought leadership to improve the health, well-being, and lives of people globally.



CYNTHIA LACONTE
CEO, Dohmen Life Science Services

Our industry will miss a tremendous opportunity if we mistake change for progress. Whether through cognitive computing or CRISPR/CAS9, technology is poised to dramatically improve human health. Yet, we find ourselves at a fork in the road: protectionism or progress. Do we continue in the comfort zone of chronic therapies or do we create cures? The latter demands new thinking about consumers, channels, incentives, and regulation. Tough stuff, but either our industry steps up to invent new paradigms or Silicon Valley will happily step in and do it for us. When was the last time you visited a record store?



VERA RULON
Director, External Medical Communications, Pfizer Medical, Pfizer Inc.

Over the past 15 years the convergence of digital technologies and the empowered consumer have had the greatest impact on the

The Social Explosion...

- ▶ **2003** — LinkedIn, which started out in the living room of co-founder Reid Hoffman in 2002, was officially launched May 5, 2003, by him and co-founders Allen Blue, Konstantin Guericke, Eric Ly, and Jean-Luc Vaillant. Today, LinkedIn is the world’s largest professional network with 300 million-plus members.
- ▶ **2004** — Facebook, the online social networking service, was launched on Feb. 4, 2004, by Mark Zuckerberg with his Harvard College roommates and fellow students Eduardo Saverin, Andrew McCollum, Dustin Moskovitz, and Chris Hughes. Now more than 1 billion people use Facebook, and the company is valued at more than \$300 billion, surpassing GE, which traces its history back to Thomas Edison and the first light bulb.
- ▶ **2005** — YouTube, the video-sharing website, was created by three former PayPal employees in February 2005. In November 2006, it was bought by Google for \$1.65 billion.
- ▶ **2006** — Twitter was created in March 2006 by Jack Dorsey, Evan Williams, Biz Stone, and Noah Glass and launched in July 2006. The service rapidly gained worldwide popularity, with more than 100 million users posting 340 million tweets a day in 2012.
- ▶ **2010** — Instagram, launched in 2010, is an online mobile photo-sharing, video-sharing, and social networking service that enables its users to take pictures and videos, and share them on a variety of social networking platforms, such as Facebook, Twitter, Tumblr, and Flickr. Today, Instagram is valued at \$35 billion and has 300-million user base.
- ▶ **2010** — Pinterest, which was first conceptualized in December 2009 by co-founders Ben Silbermann, Evan Sharp, and Paul Sciarra, was launched in March 2010 as a prototype and made available to a small group of people. Last March, the image bookmarking site was valued at \$11 billion.



life-sciences. This includes clinical trial conduct, medication management, and sharing of data and medical information through the use of connected health. The life-sciences industry is realizing that patients are not going to wait for us but are researching and creating technological solutions to manage their own health. The inclusion of patients in designing new treatments and addressing their unmet needs is set to fully transform the life-sciences and healthcare.



VARADHARAJAN KRISHNAMOORTHY
Advisor,
Danvantri Associates

The life-sciences industry is that golden triangle that connects patients, HCPs, and the pharma/healthcare industry. With disruptive technologies touching the lives of people in all walks and spheres of life, the life-sciences industry is no exception. One single aspect that stands out is the information that is available and the behavior connected to it. In simple terms, the industry needs to be more patient-centric and is doing it through the HCPs who are the direct providers who deal with equipped patients. Executing patient-centricity via HCPs and preparing the whole organization toward this goal is the single biggest transformation that I see all around. The life-sciences industry starts with intermediates/raw materials and ends with patient compliance. Regulations exist all throughout. Additionally, most markets have become increasingly regulated. So the cost of doing business has gone up. Technology has shrunk the world, which means more competition. The pipelines for innovators have dwindled. Collaboration models are yet to take off. The needs of the patient world and commerce do not always sync. The pressure on growth is felt. People have been struggling to switch from legacy systems to the future of #socabiz models. The enormity of these factors is striking some in the industry resulting in paralysis by analysis. But, move we must, and fast too. There are disruptive technologies and opportunities out there awaiting the industry.



SCOTT COTHERMAN
Principal,
Scott Cotherman
Enterprises LLC

Innovation in technology and its applications to healthcare has been profound. Rising from the dot-com bust of the late 1990s, to the decoding of the human genome in 2001

HealthTech Trends

Wearable technology

More than **80%**

of consumers said an important benefit of wearable technology is its potential to make healthcare more convenient.



Telehealth

70%

of patients are comfortable communicating with their healthcare providers via text, em-mail or video, in lieu of seeing them in person.



Electronic health records

71%

of physicians have adopted an electronic health record (EHR), and 85% of adopters have an EHR certified for meaningful use.



Cloud-based technology

As providers and patients seek to become more agile, cloud computing is expected to grow at a

20%

annual rate until 2017, when it will reach a market size of \$5.4 billion.



Source: The Wearable Future, PwC, October 2014; NTT Data, Trends in Telehealth (2014) ; Physician Motivations for Adoption of Electronic Health Records, ONC Data Brief, December 2014; The true rate of cloud adoption in healthcare, Cloudtech Courtesy of: Philips

that led to precision medicine and personalized healthcare, to the proliferation of mobility based technology applications, there has never been a better time for enhancing, prolonging, and saving human lives. Today, young entrepreneurs are collaborating in health-technology incubator and accelerator set-ups all over the country to bring their innovations to market. Investors are fueling their fire. It's all very exciting for the future of health and wellness.



WILLIAM KING
Founder and Executive
Chairman, Zephyr Health

The vast availability of data, now known as Big Data, is transforming the way life-sciences companies do business. With more than half of life-science products unable to achieve their sales forecast due to inaccurate, outdated, or disconnected data, and even information overload, our industry is realizing the need for solutions that can connect and interpret that Big Data in a timely manner. The insights that come from these integrated platforms can produce confident decisions for a product across its life cycle through to successful commercialization, and lead to cost-savings and competitive advantage while meeting patient need.

STEPHEN HOELPER
VP of Marketing and New Product
Development, MediSolutions

The movement toward meaningful use attestation has placed the entire industry on its



head. There's a call for digital health solutions designed to coordinate patient and physician interactions while facilitating better care. Unfortunately, the reality has proved different. Many digital health solutions have introduced the unintended consequence of communication gaps that make care delivery more difficult and create silos of participants. In thinking of our large network of physicians and pharma partners, we've shifted our focus to simplifying healthcare by closing these gaps with a combination of new digital tools and traditional media, thereby facilitating meaningful conversation and collaboration among all stakeholders.

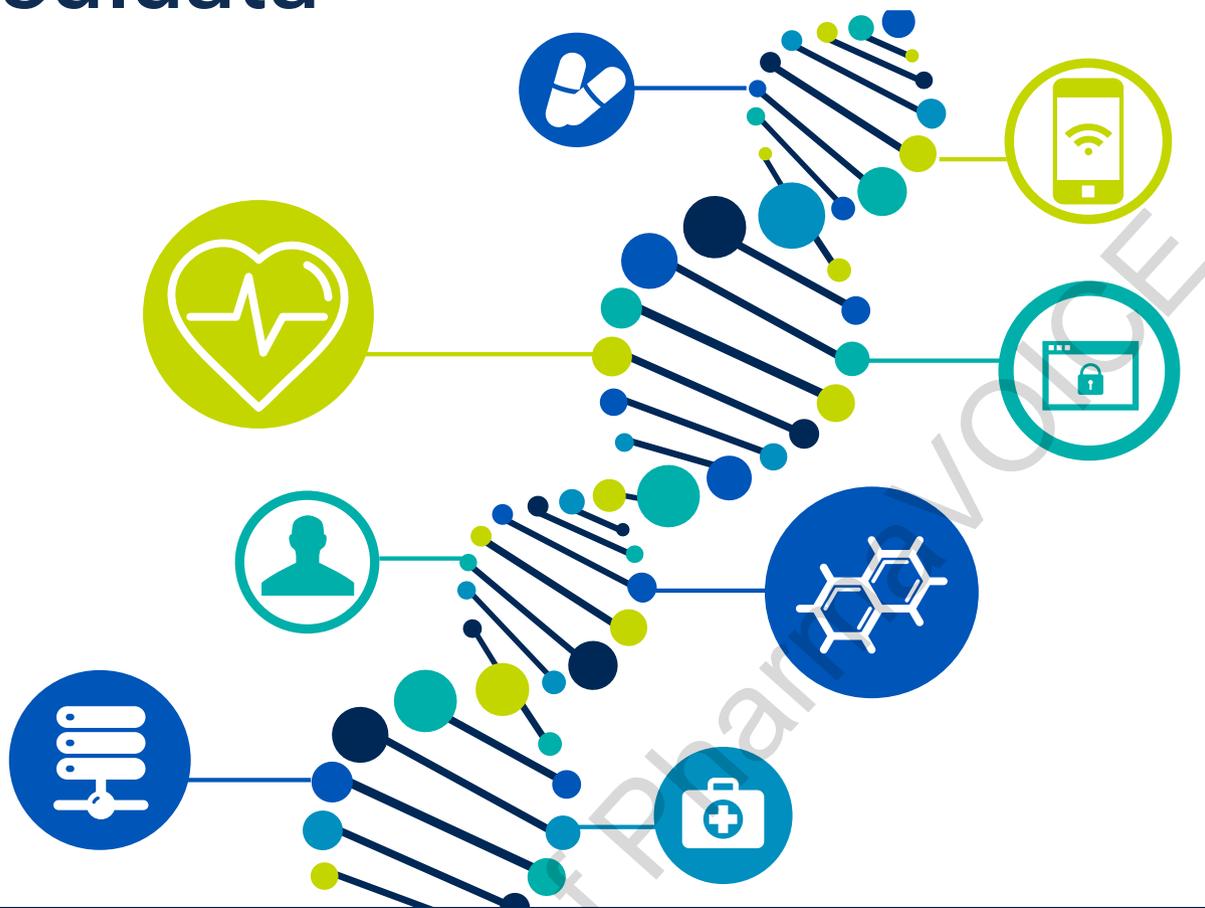


SUJAY JADHAV
CEO, goBalto

The need for more efficient clinical trials — widely acknowledged as complex and slow — has driven greater use of cloud-based solutions, especially with the rise in globalization. Stakeholders have been embracing cloud-based solutions such as electronic data capture (EDC), clinical trial management systems (CTMS), electronic trial master file (eTMF), and Study Startup (SSU) attempting to stem the average 6.7 year clinical development cycle — automating tasks that remain paper-based or rooted in spreadsheets. It's important to highlight the value of emerging technology that is integrated in the eClinical stack, which

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medidata



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streamlines bottlenecks allowing stakeholders to better adhere to timelines and budgets.



JOSEPH DUSTIN
Principal, Mobile Health,
Medidata Solutions

Paper was the standard for collecting patient data in clinical trials 15 years ago. Palm Pilots and other PDAs were just emerging as “revolutionary connected technologies” to capture the patient voice. Today, smartphones, sensors, wearables, apps, and other easy-to-use technologies are helping us collect remote, objective data in real time and better measure patient outcomes. Intelligent analytics and predictive algorithms are giving us greater insight into disease progression and patients’ overall health status. Such advances are enabling increased patient engagement in trials and the emergence of smarter, more precise clinical data to fuel the discovery of vital new medical treatments.



MATTHEW SMITH
Senior VP, Global
Commercial Operations,
SynteractHCR

The one thing that has changed dramatically is technology. Our approach has changed so that we can meet evolving sponsor demands in areas such as electronic data capture and source documentation, adaptive trials, and project intelligence. We need to continually stay up to date with technological advances in the industry to continue to bring tomorrow’s treatments to the patients who need them.



BRIAN OVERSTREET
CEO and Founder,
Advera Health Analytics

By far the biggest transformation over the past 15 years has been the creation, curation, and explosive growth of real-world data. The success of the next 15 years will be determined by how well we ensure the accessibility of those data and how we transform those data into actionable intelligence that can drive the product life cycle from clinical development through post-marketing surveillance.

MATT WALLACH
President and Co-founder, Veeva Systems

Fifteen years ago, every life-sciences company



was using client/server software technology for CRM, content management, master data management, and many other needs. Today, most have switched to cloud computing solutions, dramatically improving usability, increasing flexibility, and lowering total cost of ownership. This is creating opportunities not even considered in 2000.



**EDMUNDO MUNIZ,
M.D., PH.D.**
CEO, Certara

We have seen increased use of biosimulation — modeling and simulation — to inform drug doses and drive greater precision in drug labels, which positively impacts payers and patients. Regulatory agencies have also embraced this technology as an integral part of the drug development process. In the past, regulators didn’t hold sponsors responsible for understanding how their drug would work in untestable clinical scenarios — the almost infinite number of potential drug-drug interactions, special populations such as pediatric patients, pregnant women, and those with complex co-morbidities, or rare diseases with very few patients — but with the adoption of biosimulation, that’s no longer the case.



JON BRIER
Product Manager,
Revitas Inc.

The dramatic increase in government regulations during the past 15 years has validated manufacturers’ need to automate contract management procedures. Spreadsheets and homegrown solutions aren’t robust enough to handle the increasingly complex demands of calculating rebates and managing partners. Modern contract life-cycle management software minimizes errors and delivers consistent numbers, ultimately improving manufacturer efficiency and profitability, and avoiding government fines and rebate overpayment. Moving to automated contract management has also altered the job description for compliance managers. Today’s systems require analytical minds who can interpret data and find trends, then apply that information to create meaningful change in an organization.

MICHAEL TAGUE
Managing Director,



HealthAnswers Education

Sales training has benefited tremendously by an infusion of learning technology. Sure the iPad is a great selling tool but it is an even better training tool. HealthAnswers has evolved with that revolution and helped our clients leverage the best the iPad offers for all their sales training needs, for example pure app-based e-learning modules, games, virtual preceptorships, and live meeting apps. I remember when training was all about print modules, sales meetings, and training workshops. There is still a place for those tactics but, boy, have things changed — and for the better. Next wave of change is learning analytics.



MATT GIEGERICH
Chairman and CEO,
Ogilvy CommonHealth
Worldwide

By far, the biggest change in healthcare communications over the past 15 years has been the near-total democratization of health-related content via the Internet and related digital technologies. With the genie now living comfortably out of the bottle for more than two decades, instant access to the world’s volume of health-related information has put God-like power in the hands of the masses and forever altered the landscape of marketing communications, content creation and consumption, and customer engagement.

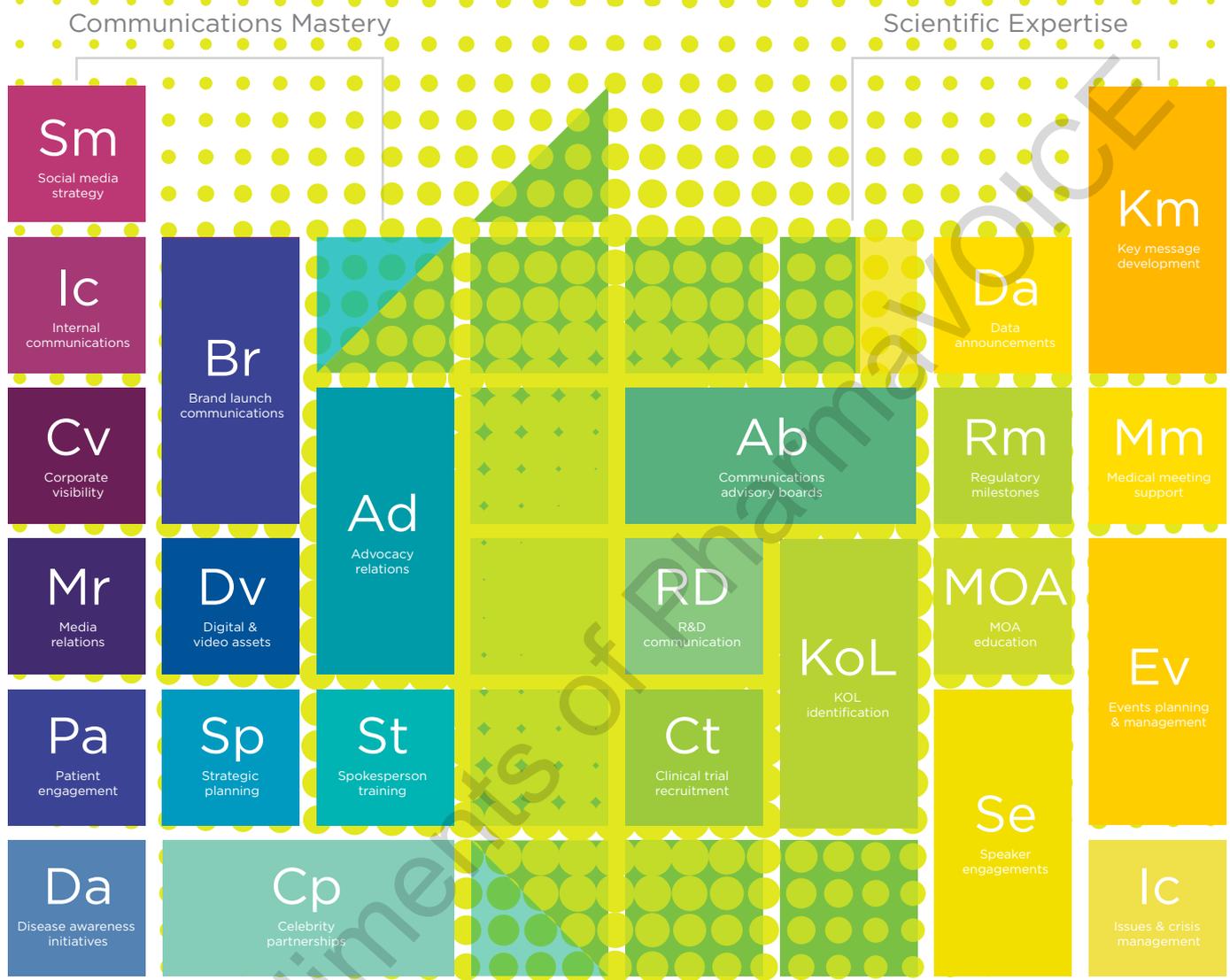


LORI GRANT
President, Klick Health

The last 15 years have been incredibly transformative in the evolution of digital health. For starters, the term digital health didn’t even exist 15 years ago. The Internet has matured to the point that it has become the first place patients go for medical information. Technology has enabled the personalization of almost everything, empowering the patient to become a partner in his or her own health management. The potential of personalized treatments through genome sequencing and pharmacogenomics is thrilling. And of course, the advent of mHealth, telehealth, and remote monitoring devices has fueled the ability to have better access to data, further empowering the patient. Klick has always had a strong foundation of being data driven and we look forward to continuing to help patients, and

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As a full-service healthcare **PR** agency,
Tonic has the art of communications down to a science.



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Maryellen Royle, president
toniclc.com





their HCP partners, in their journey using the power of their data.



ERIK DALTON
Executive VP, Healthcasts

Pharma-HCP communication, and more generally HCP information consumption, has changed dramatically in the past 15 years. We have evolved from nascent EMRs to fully integrated medical records — from dinner meetings to virtual meetings — and from traditional advertising to personalized content marketing strengthened by data. The Internet, the abundance of information available, and the multiple devices physicians use to access this information have transitioned the pharma-physician relationship from a one-way push of information to a two-way stream of communication propelled by HCP needs and preferences.



MARYELLEN ROYLE
President, Tonic Life Communications

Our obsession with 24/7 connectedness through digital, mobile, and wearable devices has changed the way we receive and consume healthcare information, ultimately affecting our expectations from doctors, insurers and products/services, and providers. As PR professionals in a regulated industry, we have focused our communications efforts to support this real-time consumer education, engagement, and empowerment on behalf of our healthcare clients.



WENDY BLACKBURN
Executive VP, Intouch Solutions

We have witnessed an incredible transformation in healthcare and also technology. And those two industries have become intricately intertwined. Patients are tracking and treating their health with technology. Physicians are diagnosing and doctoring virtually. We carry our worlds around in an amazing pocket-sized computer. Things have come a very long way since the brochure-ware website.

DIONISSIS NIKOLOPOULOS
CEO, Aqurance

These have been exciting years for the life-sciences. Mobile and digital technology have



enabled us to optimize sales and marketing actions, to show the right path into tons of available data and to assist pharma companies to achieve better customer engagement. During the past years, we've seen sales and customer excellence transform into more eligible and flexible departments by incorporating top of breed technology into daily operations. Combining digital services, market research, predictive analytics, and valuable insights many organizations are reaching digital transformation. I believe more exciting things are yet to come.



BRIAN ROBINSON
Chief Marketing and Strategy Officer, Aptus Health

Pharma marketers have reached a tipping point. With more than half of U.S. physicians practicing in health systems — and a third of them saying they “never” see reps — the blistering pace of medical advancements, and increasing pressure on pharma to deliver

value, existing commercial models no longer work. Pharma clients are re-evaluating their approach — creating an integrated, engaging digital experience for their targets that breaks through the noise with relevant content that drives better decisions, whenever and wherever they need it.



KIM JOHNSON
President, Palio, an inVentiv Health company

It is difficult to point to one overarching change in an industry that has undergone unprecedented change across so many areas of the business. With personal interest in technology-driven innovation, I would point to the massive change in sales and marketing models. Pharmaceutical companies have fundamentally changed the way they engage their customers and constituents with sophisticated salesforce automation and digital sales platforms, robust nonpersonal channels, and behavioral-based CRM programs. And though we may have room to grow with social media, active education and marketing on Facebook, Twitter, Instagram, and YouTube were far from conceived 15 years ago.

► Clinical Development

In 2015, FDA's Center for Drug Evaluation and Research (CDER) approved 45 novel new therapies — significantly more than the average of 28 approved during the previous nine years of this decade — many of which offer many patients new treatment options for serious and life-threatening conditions.

“During the next five years, we expect to see a surge of innovative medicines emerging from R&D pipelines, as well as technology-enabled advances that will deliver measurable improvements to health outcomes,” says Murray Aitken, IMS Health senior VP and executive director of the IMS Institute for Healthcare Informatics. “With unprecedented treatment options, greater availability of low-cost drugs, and better use of evidence to inform decision making, stakeholders around the world can expect to get more ‘bang for their medicine buck’ in 2020 than ever before.”

In its latest study, the IMS Institute highlights the following findings:

- By 2020, technology will be enabling more rapid changes to treatment protocols, increasing patient engagement and accountability, shifting patient-provider interaction, and accelerating the adoption of behavior changes that will improve patient adherence to treatments.

- Every patient with multiple chronic conditions will have the potential to use wearables, mobile apps, and other technologies to manage their health, interact with providers, fellow patients, and family members.
- The ubiquity of smartphones, tablets, apps and related wearable devices, as well as electronic medical records and exponentially increasing real-world data volumes, will open new avenues to connect healthcare while offering providers and payers new mechanisms to control costs.

Research from the analyst company Dickson states that while estimates vary on how much it costs to bring a new drug to market, a recent study from the Tufts Center for the Study of Drug Development (CSDD) pegs the average total at \$2.9 billion. But, 95% of medicines fail during development, and only two in 10 recoup their research and development costs.

Once drugs lose patent protection, generics siphon off up to 90% of sales. The average annual savings from switching to generic medications is estimated to be \$420 per consumer.

IMS Institute states that generic medicines will continue to provide the vast majority of the prescription drug usage in the U.S., rising

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from 88% to 91% to 92% of all prescriptions dispensed by 2020. Spending on medicines in the U.S. will reach \$560 billion to \$590 billion, a 34% increase in spending over 2015 on an invoice price basis.

While drug pricing is commanding significant amounts of attention in Washington, PwC analysts say the life-sciences industry should keep its eye on regulatory reform packages slowly working their way through the halls of Congress and the FDA, which could have wide-ranging impacts on how drug and medical device products are researched, regulated, and even priced.

Some of the most impactful long-term changes to the life-sciences sector in 2016 likely will emerge from the ongoing debate regarding the reauthorization of the FDA's user fee programs. The programs, which fund much of the FDA's regulatory activities for drugs (branded, generic, and biosimilars) and medical devices are set to expire in September 2017.

Frequent public negotiations between the FDA and industry over possible changes already are under way and will continue until the end of 2016, paving the way for a 2017 passage. Already at issue: The speed and funding of FDA reviews, the elimination of backlogs of certain applications, and identification of ways to allow patients to participate in the review process.



MARK WOLFF, PH.D.
Principal Industry Consultant, Chief Health Strategist, Health & Life Sciences Global Practice, SAS

By most scientific, regulatory, and economic metrics, the pharma industry has experienced remarkable success over the last 15 years. Yet, during this same period the industry also endured profound challenges and disruptions to nearly every part of the discovery, development, and commercialization process. Looking back from the perspective of 2015, the industry might be tempted to think that the worst may be over. However, looking ahead, it faces transformative and existential obstacles. The future of the industry may well belong to those companies that can address the related challenges of patient stratification and the reinvention of the clinical trial.

UMA ARUMUGAM, M.D.
Director, Clinical R&D, Early Phase Services, ICON

One of the biggest changes in the past 15 years that I have witnessed in the life-sciences



industry is a more refined understanding of clinical medicine, specifically disease pathologies, at a molecular level in pharmaceutical drug development. This has eventually led us to explore path-breaking endeavors

such as precision medicine, leading the way forward to pursue assets with a high probability of success and of significant value. This has not only introduced efficiencies, but more importantly helped us design smarter trials, thereby bringing drugs to market that profoundly improve the quality of life for patients.



DONALD DEIESO, PH.D.
Chairman and CEO, WIRB-Copernicus Group

Precision medicine is the most exciting new frontier in clinical research. Gone are the days of the one-size-fits-all drug; we are now able to tailor the choice of drug and its recommended dosage to the individual patient, accommodating unique factors such as age, genetics, and comorbidities. New types of trial designs enable us to address more orphan and rare diseases than ever before. And by incorporating innovations such as biosimulation and statistical modeling into the preclinical phase, we are able to make clinical trials safer for human volunteers and more predictable for their sponsors.



MELISSA EASY
Founder, President DrugDev SiteStart, DrugDev

After being frustrated with the inefficiencies in the clinical trial process I started DrugDev as a way to improve the collaboration between investigators and sponsors, so I'm excited to see the growing commitment among sponsors to share information and work together to streamline clinical trial operations so more promising drugs can be tested and developed. Groups like the Investigator Databank and TransCelerate are driving industrywide collaboration and standardization to improve the efficiency and effectiveness of clinical trials. We applaud their efforts to reduce the burden on sites and accelerate the clinical trial process.

SUSAN DALLABRIDA, PH.D.
VP, Clinical Science and Consulting, ERT

Clinical outcome assessments, especially elec-

Drug Facts: Through the Years

DEVELOPMENT COSTS

2000s–early 2010s = \$2.6 billion
1990s–early 2000s = \$1.0 billion
1980s = \$413 million
1970s = \$179 million

R&D SPENDING (BY PHARMA MEMBERS)

2014 — \$51.2 billion (est.)
2013 — \$51.6 billion
2012 — \$49.6 billion
2011 — \$48.6 billion
2010 — \$50.7 billion
2009 — \$46.4 billion
2008 — \$47.4 billion
2007 — \$47.9 billion
2006 — \$43.0 billion
2005 — \$39.9 billion
2004 — \$26.0 billion

MEDICINES IN DEVELOPMENT

- ▶ Medicines in development around the world = **7,000**
- ▶ Potential first-in-class medicines in clinical development globally = **70%**
- ▶ Medicines in development to treat rare disease = **More than 4,502**

APPROVALS

- ▶ Medicines approved 2014 = **51**
- ▶ Medicines approved since 2000 = **more than 500**
- ▶ In the 30 years since the Orphan Drug Act was established, more than 500 orphan drugs have been approved, with **more than 230 approved in the last decade alone**
- ▶ Only **2 of 10** marketed drugs return revenue that match or exceed R&D costs

SALES

Generic share of prescriptions filled
2000 = 49%
2013 = 88%

Source: PhRMA



tronic clinical outcome assessments (eCOA), have shifted the source and focus of clinical data from the clinician to the patient. The past 15 years have marked a significant course correction in how pharmaceutical researchers regard the patient's voice as the primary clinical data source. Global regulatory mandates and consistent scientific evidence confirm that eCOAs collect data that are attributable, legible, contemporaneous, original, and accurate. On-device calculations and branching logic increase study power; integrations with medical devices collect subjective and objective data simultaneously; and mobile eCOA enables remote patient monitoring, generating a higher safety and data quality standard.



NICHOLAS SPITAL
VP, Clinical Services,
Chiltern

The digitization of clinical research must be one of the most impactful realizations over the past 15 years with EDC, IRT, eCOA, eTMF, imaging and other electronic modalities becoming ubiquitous in an increasingly paperless world. This evolution has allowed the industry to work in real time, becoming more efficient and more nimble and making drug development safer in the process. Look for this to continue in the coming years via mHealth technologies, which will increase accessibility to clinical research, while giving patients and caretakers a voice in how we develop new treatments.



CHITRA LELE, PH.D.
Chief Scientific Officer,
Sciformix Corp.

The importance of drug safety increased significantly after the Vioxx withdrawal from the market in 2004, with a vast change in stakeholder participation. To protect patient safety and comply with regulations, organizations developed systems to adequately capture, process, analyze, and submit reports of adverse events of their products. With the increased focus on product safety, outsourcing safety data management has become commonplace, with cost-effective locations being leveraged. Advancements in informatics-based methods have facilitated global initiatives to transform the product safety system to make it proactive, clinically relevant, and driven by benefit-risk consider-

ations rather than only safety. All stakeholders continue to strive to pave new paths to enhance benefit-risk assessment, communication, and implementation.



DOREEN LECHNER, PH.D.
Program Director, Clinical
Trial Sciences, Biopharm
Educational Initiative,
Rutgers University

From a global view, risk management and signal detection are one of the largest changes in the area of pharmacovigilance in the past 15 years. Due to the limitations of identifying product risks during the investigational phase of drug development, there are now specific guidance and legislation focusing sponsor organizations on understanding the risk profile of marketed products.



STEPHEN WEBB
Consultant/Managing
Member,
SLW Holdings LLC

I have seen the industry evolve from being almost solely focused on randomized controlled trials as the mainstay for evaluating clinical efficacy and safety, to now also recognizing the value and benefits of observational studies in real world research (RWR) to evaluate long-term product effectiveness and safety. When we founded Registrat in 1997, we were one of only a few niche providers with extensive expertise and experience in the design and conduct of registries and observational studies. Today, sponsors, regulators, payers, and providers are more broadly educated regarding the various design and applications of these studies, including patient-centered research.



JAY DIXON
Senior VP, Global Quality
and Compliance
PPD

A major paradigm shift in the past 15 years of drug development has been the maturation of the relationship between biopharmaceutical companies and contract research organizations in collaborating as deeply engaged partners in the enterprise of improving health. Looking ahead, our continued focus is on driving innovation and efficiency to help our customers bend the cost and time curve of drug development to deliver life-changing therapies to patients.



NEIL GRAY
Senior VP, Medical Affairs,
inVentiv Health

The biggest changes that I've seen permeate the industry over the past 15 years have been the reach of OIG and FDA, the fear generated by possible fines and CIAs, and in light of all of this, the growth of medical affairs as a discipline within the industry.



CHRISTINE PIERRE
President,
Society for Clinical
Research Sites

The evolution of the complexity of and necessity for site sustainability has reached an all-time high. In response to the many influences contributing to this crisis the Society of Clinical Research Sites, a global trade organization, was formed in 2012 with a mission to "unify the voice of the global clinical research site community for greater site sustainability." SCRS' growth directly relates to the importance of the SCRS' mission and supporting the need to advocate, educate, connect, and mentor sites. With sites now having an active voice and community, the momentum can continue to ensure site sustainability is achieved.



APRIL MULRONEY
Managing Director,
Payments,
Medidata Solutions

Clinical trial sites continue to play an important role in advancing drug development, but financial burdens are still contributing to high investigator turnover. Without the right tools, life-sciences organizations have had to rely on manual spreadsheets to process payments, resulting in unreliable, time-consuming calculations, and poor visibility into study balances. Foreign exchange and tax intricacies further complicate the issue in global trials. Today, the industry is alleviating these burdens. New global legislation on payment transparency has accelerated the need for efficiencies and accuracy, while new technologies redefine accounting processes, helping to eliminate financial reporting errors and reduce reimbursement delays.

LYNN MEYER
President and Managing Partner,
IntegReview IRB

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Over the last 15 years, I believe the biggest change in the human subject protection space was the formation and industry acceptance of accreditation of human research protection programs. By meeting the standards of accreditation, protecting the rights and welfare of study participants has resulted in process improvements by all involved parties. IntegReview IRB is proud to be among those organizations that earned and maintains full accreditation.



BRAD VINCE, D.O.
CEO and Medical Director,
Vince & Associates Clinical
Research, an Altasciences
Company

The industry has evolved in recent years to more frequently incorporate special populations in Phase I studies to obtain an earlier read on potential efficacy data. As a result, our company has adapted by building a new clinical pharmacology unit to incorporate changes in technology as well as allow us to sequester special populations for certain clinical trials in an effort to focus on quality data and the retention of these volunteers.



JOAN BACHENHEIMER
Founding Principal,
BBK Worldwide

Understanding the role that well-practiced recruitment plays in study success and investigator satisfaction is on the rise. The recognition that market science and research science must align earlier, however, is less understood, yet doing so can greatly improve study outcomes. What's more, this slower-than-needed adoption threatens the practice of patient-centricity because at the heart of market science is an understanding of and sensitivity to the needs of all key study stakeholders — especially patients.



CATHY SIGLER, PH.D.
Executive Director, Safety,
Epidemiology, Registries &
Risk Management, UBC

Data gained from post-marketing studies have moved from a “nice to know” to “must have.” Clinical development and product safety have greatly expanded beyond Phase III. New regulations require studies to assess

known risks or signals of serious risks in the marketplace, resulting in an increased volume of studies and data and in a greatly improved understanding of the health effects of products in real-world settings. This public health orientation acknowledges the truth that benefit-risk is best assessed not solely in Phases I-III, but through studies of use and effects in populations.



DR. GRAHAM WYLIE
CEO, Medical Research
Network (MRN)

The single-most important change in my professional life over the last 15 years has been the creation of our highly specialized Home Trial Support (HTS) service. MRN formed 10 years ago when there were only three companies in the world offering clinical trial services in the home, and only MRN outside North America. Initially HTS was deployed in trials with major recruitment failure, but since then it has become mainstream, utilized in multiple therapeutic areas in more than 37 countries, boosting patient recruitment and retention.



KEITH MURPHY
Chairman and CEO,
Organovo

The biggest change from the perspective of 3D tissue is the transformational achievement of in vitro tissues that are 100% cellular and 100% human. This has resulted in a number of breakthrough moments, most recently the achievement of an accurate liver fibrosis model that has been shown to match clinical pathology both from

a histologic and gene expression perspective, and is poised to revolutionize discovery in this area. Those results are expected to translate to fibrosis in other tissues as well, including kidney where additionally the first in vitro model with proper transporter function has also finally been achieved.



JIM BLAIR
Partner,
Domain Associates

Over the last 15 years the biggest change in the life-sciences industry would be the opportunities for investment in the genomics space. In 2000, the Human Genome Project released its first draft of the complete human genome. Since then we have witnessed an explosion in genomics technologies, which have lowered the cost of sequencing to under \$1,000 per genome. This accessibility has just begun to give insight into rare diseases, cancer biology, and microscopic organisms that inhabit every nook and cranny of our world. Each of these growing fields offers potential for investment in novel treatments and personalized healthcare.



ROSS PERRY
President,
CHX Technologies Inc.

The biggest changes in oral healthcare have been two key concepts: the concept of risk for poor oral health and the management of oral dysbiosis. When combined, these concepts support a new approach to preventive care which is more affordable, painless and value-based. In short, better dental care at lower cost.

► Cancer

According to PhRMA, since peaking in the 1990s, cancer death rates have declined almost 22%. Approximately 83% of survival gains in cancer are attributable to new treatments, including medicines, as well as other factors.

In 2001, cancer was considered one homogeneous disease. Today, the category is now considered to encompass specific diseases, which are now being addressed by targeted cancer therapies designed to interfere with specific molecules necessary for tumor growth and progression.

In 2016, there will be an estimated 1,685,210 new cancer cases diagnosed and 595,690 cancer deaths in the United States.

In President Obama's last State of the

Union speech, he announced a national effort to cure cancer with Vice President Joe Biden heading up the initiative.

After the announcement of this moon shot, President Obama stated, “For the loved ones we've all lost, for the family we can still save, let's make America the country that cures cancer once and for all.”

In February, Illumina, the San Diego DNA sequencing company, announced that it is setting up a new company to help create a blood test for cancer detection. Illumina is the majority owner of Grail, which has raised \$100 million in a Series A funding round. Company executives hope that by detecting cancer early before symptoms manifest, this may be human



kind's best shot at improving how many survive worldwide and that this is a turning point in the war on cancer.

In a statement, Jay Flatley, Illumina CEO and chairman of Grail, said by enabling the early detection of cancer in asymptomatic individuals through a simple blood screen, we aim to massively decrease cancer mortality by detecting the disease at a curable stage.



RAKESH DIXIT, PH.D.
VP, R&D, Global Head, Biologics Safety Assessment, MedImmune

The biggest transformative change over the past 15 years has been the emergence of biologics, especially in cancer treatment. The immune checkpoints inhibitor-based immunotherapy has rejuvenated the entire field of both heme and non-heme solid cancers. The recent success of anti-PD1 antibody (Keytruda) in treatment of terminal melanoma that had spread to the brain in President Jimmy Carter is worth noticing. The immunotherapy has given new hope to cancer patients and it is truly transformative.



ALISON BATEMAN-HOUSE, PH.D.
Rudin Postdoctoral Fellow, Division of Medical Ethics, New York University School of Medicine

In 2015, Janssen Pharmaceuticals and New York University partnered to create CompAC, the Compassionate Use Advisory Committee, an international, interdisciplinary, expert group that handles compassionate use requests. The pilot involved daratumumab, a cancer-fighting biologic in short supply prior to FDA registration. Requesters completed a standardized form from

which the patient's name, sex, and nationality were removed before review by CompAC. Within five business days, CompAC recommended whether the drug should be provided. Through these and other innovations, CompAC offers a fair process for patients seeking compassionate use and a transformative model for handling compassionate use requests.



GLEN DEVRIES
President and Co-founder, Medidata Solutions

Fifteen years ago, basic molecular biology research spanning the previous 30 years was leading to early and tremendously exciting approaches to treating cancer. Today, the deeper understanding of the fundamental biology behind cancer and other diseases is enabling more targeted and effective approaches to not just managing various indications, but curing ones previously regarded as incurable. Meanwhile, in clinical trial technology, we've gone from the first steps of leveraging the web to an environment where using powerful enterprise and industry-focused cloud platforms is becoming a standard of care for R&D, a practice that is accelerating innovation and groundbreaking medical advances.



SIMONA KING
Head of Finance, Enterprise Services, Bristol-Myers Squibb

The fight against cancer and advances in that area have been some of the biggest developments I've seen in the pharmaceutical industry. Most notable is the innovation in immuno-oncology cancer treatments that seek to harness the body's own immune system to fight tumor cells.

FAST FACT

MORE THAN 225 MEDICINES WILL BE INTRODUCED BY 2020, WITH ONE-THIRD FOCUSED ON TREATING CANCER. DISEASE TREATMENTS IN 2020 WILL BE TRANSFORMED BY THE INCREASED NUMBER AND QUALITY OF NEW DRUGS IN CLUSTERS OF INNOVATION AROUND CANCER, HEPATITIS C, AUTOIMMUNE DISORDERS, HEART DISEASE, AND AN ARRAY OF RARE DISEASES. DURING THE NEXT FIVE YEARS, AN ADDITIONAL 75 NEW ORPHAN DRUGS ARE EXPECTED TO BE AVAILABLE FOR DOZENS OF THERAPEUTIC AREAS THAT CURRENTLY HAVE LIMITED OR NO TREATMENT OPTIONS.

Source: IMS Health

The good news for consumers is that the costs for generics are 80% to 85% lower on average than those of patented drugs.



ANN MOHAMADI
Managing Director — Pharmaceuticals & Life Sciences, PwC

One of the biggest changes we've seen is the evolution of the healthcare delivery model and physicians becoming affiliated and/or employed within integrated delivery systems. This shift has changed many things, including how care is delivered, how outcomes are measured, how value is demonstrated, and how risk is shared across multiple stakeholders. Commercial success of new products will require an in-depth understanding of this shift and the needs of the new stakeholders making key decisions.

► Business Models

As the life-sciences industry continues its transformation into a new health ecosystem with a new health economy to address multiple stakeholders, new delivery platforms, and new players entering the arena, business as usual is no longer accepted or acceptable.

Life-sciences companies of all shapes, sizes, and functions are changing how business is done and how they do business. Pricing will remain front and center as a major operational concern as well as the patent loss for several major brands.

According to Matt Zajechowski of Dick-

son, AstraZeneca is one company in 2016 that is losing two major drugs from patent protection — Crestor and Seroquel XR — worth a combined annual revenue of \$7.34 billion. The top five biggest patent losses in 2016 per holder after AstraZeneca are Daiichi Sankyo, Merck, Abbott, and ViiV.

He says of course, there's room here for consumers to gain. Four major HIV drugs also are going off patent in 2016: Epzicom, Trizivir, Norvir, and Kaletra, with a current cost-per-pill at \$39.57, \$11.07, \$8.83, and \$7.22, respectively.

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MICHELLE KEEFE
President and CEO,
Publicis Touchpoint
Solutions

Half of the physicians in the United States are now employed by a health system and this new landscape is challenging payment systems, shifting reimbursement based on how much care is given to how effective it is. This shifting focus will call for a renewed emphasis on value-based care delivery. This change is warranting the need for more B2B selling with key account managers to work with key non-clinicians who will increasingly be making decisions around treatment protocols to improve the quality and reduce the cost of care.



THERESA GRECO
VP, Life Sciences,
LexisNexis

The life-sciences product portfolio has shifted to focus on specialty, oncology, and rare diseases. This shift, combined with ACA regulations, has led to a transformation in commercial models that focus on the full system of healthcare and the increased importance of understanding the relationships and influences that exist among entities within the healthcare network and the impact on patient outcomes.



JOANNE KAMENS, PH.D.
Executive Director,
Addgene

I work at a nonprofit biotech organization, which seems like an oxymoron, but in fact novel business models to further science and healthcare are becoming more common. Partnering arrangements between commercial and nonprofit organizations are on the rise as many explore new ways to accelerate solutions for human health. I predict we will see more of these types of alliances bringing novel resources to our most critical healthcare challenges.



JAY LICHTER, PH.D.
Managing Director, Avalon
Ventures, President,
COI Pharmaceuticals

The biggest change in venture investing over the last 15 years has been expanded early-stage scientific innovation. To capitalize

on these opportunities, we realized we needed to streamline the process of creating new biotech companies that could quickly find, validate, and translate emerging technologies into medical advances. One of the major handicaps for a new biotech is the “starting up,” so we created COI Pharmaceuticals, a community of innovation that provides operational support, mentorship, and a fully equipped R&D facility. This has created a pipeline of companies pursuing early-stage discovery across various therapy areas.



BETSY JUSTASON LAHUE
Worldwide VP, Health
Economics and Market
Shaping, Becton,
Dickinson and Company

Industry-leading management teams universally recognize the importance of health economic and access specifications in the target product profile and re-organize to empower value and access leadership. Fifteen years ago, very few life-sciences leaders accepted value and access inputs as go/no-go requirements in portfolio decisions. Today, innovative technologies cannot progress through development without multiple pauses to ensure evidence generation and commercialization plans sufficiently address the value demands. Since meeting value and access requirements are as critical to drive growth as the traditional R&D and regulatory hurdles, effective senior management teams now include this expertise as a stand-alone function.



DONNA WRAY
VP, Digital & Multichannel
Marketing, TGaS Advisors

eMarketing centers of excellence were in and out of fashion with the various Internet booms and busts over the past 15 years, but in 2016, we see that the vast majority of pharmaceutical companies have centers of excellence in digital and multichannel marketing that are growing over time. According to our study of pharmaceutical marketers across 19 of the top 50 pharma companies, multichannel campaign management is the top area of importance to successful pharmaceutical marketing and at the core of these groups' responsibilities. What was an “org du jour” is now a crucial part of an effective organization.

ANDREW THORN
Senior VP, Integration Strategist,
Trio, an FCB company



Perhaps the last 15 years may be best summed up in a word — empowerment. Small pharma companies have become empowered because technological advances and the ubiquity of the Internet has, in many

ways, leveled the playing field and allowed them to compete where they could not previously. Pharmaceutical marketers, in general, has been empowered to think globally and act locally, giving rise to amazing synergies and the globalization of strategies and the ability to then measure those strategies with analytic tools not dreamed of a decade ago. The patient has been empowered to make much better decisions and participate in his or her own healthcare in ways not previously possible through the advent of everything from digital health trackers, mobile disease tools, and devices and of course, research and community sites that have given rise to a new social component to healthcare. And, healthcare providers have been empowered to research and identify new, better patient solutions — treat each and every patient with a more robust set of options and chart, at their discretion, their own journey through marketing claims and brand promises.



HELEN LAWN
Managing Director, Helen
Lawn & Associates PR Ltd

Fifteen years ago a large part of our business activity was providing scientific coordination, planning, and faculty management of symposia and educational meetings for pharma companies around the world. Comprehensive changes to codes of practice have resulted in any sponsored meetings or symposia being subject to much tighter regulations around content, venue choices, supporting materials, etc. This has resulted in many pharma companies now being nervous and many are unwilling to provide educational, sponsored events, fearing any off-label discussion or content presented by their KOL speakers might result in breaches to codes of practice.



KARL KRAFT
Executive Director, MRL/
Marketing Operations
Practice, TGaS Advisors

Companies are taking a more holistic approach to the medical, regulatory, and legal (MRL) review process and overall pro-



motion development. This critical business process is ripe with opportunity to optimize, including significant cost savings, improvements in time and efficiency, greater adherence, and overall quality and utilization of promotional assets. Operational support has also become less transactional and more strategic, ensuring commercial priorities and strategies are met with timely and productive discussion with the medical, regulatory and legal review teams.



ILYSSA LEVINS
President and Founder,
Center for
Communication
Compliance

Manufacturers and communication agencies are beginning to view regulatory compliance as a business enabler versus a sales suppressor. This new mindset increases launch effectiveness, accelerates digital innovation, and saves time and money. By aligning cross-functional teams around regulatory realities early in the process, upstream, companies speed up approval of creative materials that are compliant. By replacing subjective thinking with solution-focused decision-making — here’s how to achieve fair balance — companies can approve more engaging and compliant social media campaigns. By nurturing a culture of compliance built on trust and values, not process and rules, companies fuel innovation. Ultimately, the patient benefits.



JIM O’DEA
President and CEO,
Rx EDGE Pharmacy
Networks

We have seen extraordinary shifts in the retail pharmacy’s function in healthcare. Only a few years ago, immunizations were accessible only in the doctor’s office, but now are increasingly delivered by nurse practitioners in retail clinics or by pharmacists. Blood pressure monitoring, smoking cessation programs, diabetes screenings, and other wellness services are routinely offered in the pharmacy. Clinics fill a significant healthcare need and are growing in number. In-aisle educational materials are readily available to help people learn about conditions and medications. Pharmacists have expanded their clinical and consultative functions, with a more influential role in medication management and primary care. These efforts are changing perceptions about how, where, and by whom healthcare should be delivered.



FASIAL MUSHTAQ
President of Payer/Life
Sciences, Allscripts

The changing regulatory landscape, from how life-sciences companies engage with providers to value-based care, has disrupted how organizations do business. Like the rest of the industry, they want to improve patient outcomes at reduced costs, but their direct line of communication has changed. Life-sciences companies are willing to be creative and take reasonable risks — look at what they do with consumer engagement — but they struggle to define how they “fit” in the world of the Affordable Care Act. We work with several companies that are trying new ways to improve outcomes in this new world.



JAMES CASTELLO
Executive Director,
Incentive Compensation
Practice, TGA Advisors

Sales incentive compensation has undergone significant change in the last 15 years as companies have had to administer plans in an increasingly complex environment. The rise of specialty drugs, the dramatic shifts in managed care from traditional managed care organizations to ACO and IDN, and the increased public scrutiny to sales practices have combined to create more distinct selling roles, increased number of smaller, more nimble teams, and an insatiable thirst for motivational and effective compensation plans.



JAMES BURKE
Chief Strategy Officer,
Alliance Life Sciences

Over the past 15 years, we have seen changes in how pharmaceutical pricing is managed, not only in terms of “list” pricing but also in terms of the “net” price paid both by the end patient and other financial stakeholders, e.g. commercial and

government insurance programs. The complexity of agreements between stakeholders has continued to increase as all parties seek new and innovative ways to control rising costs, while still maintaining patient access to innovative medicines. That complexity has in turn led to a need for better processes and systems in place to effectively manage pricing and revenue, as well as provide valuable insight for better decision making.



MAUREEN REGAN
Partner,
MRB Partners

A big change in medical advertising has been an outbreak of independent agencies. One reason is more FDA approvals. Advertising demand increases with pipeline output. Another factor: many new drugs are in rare diseases and personalized medicine. I’ve worked in both areas, and agencies have to be nimble, collaborating with other partners, advocacy groups, and associations. Smaller, independent agencies are well-positioned for this kind of effort. These trends aren’t lost on networks. After years of selling as one-stop shops, we may see large agencies setting up small units to give the growing industry segments the attention they demand.



Laurie Cooke
CEO, Healthcare
Businesswomen’s
Association

Numerous transformations have brought significant change to our industry, such as mergers, small molecules, insurance coverage and health IT. But what remains the same throughout this time of change is the need for diversity and inclusion to harness the best thinking. While we strive for gender parity in our industry, we still see bias in the workplace and wage disparities. Now with data to prove the case for change, we are ready to solve this and invite you to join with the HBA as women leaders transform the future.

► Mergers & Acquisitions

Many analysts say the lightning-fast pace of pharmaceutical merger and acquisition activity is only heating up as drug manufacturers seek to shift their headquarters to low tax jurisdictions and take up business models that prioritize efficiency over gross R&D spending. Recently, Pfizer and Allergan unveiled an all-

stock merger that will allow the combined company, Pfizer PLC, to move its headquarters to Ireland and focus on corporate cost cuts.

The stock deal, which values Allergan at \$363.63 a share, or 11.3 shares in the merged company Pfizer PLC, is the largest merger in the pharmaceutical sector on record. Analysts

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say the new company is expected to create a biopharma juggernaut with the financial flexibility to make new investments, while also increasing profitability and returns of capital to investors.

2016 kicked off merger mania in style, with Shire's acquisition of the newly spun off Baxalta in a transaction valued at \$32 billion, which creates a giant in rare disease treatments.

The agreement brings together Baxalta's strengths in hematologic and immunologic ailments with Shire's capabilities in lysosomal storage, gastrointestinal, and endocrine diseases.

Just by looking at the top 15 pharma companies in 2001 compared with those in 2015, one needs a score card to tell who the players are — or were.

With so many mergers, it takes a pharmaceutical historian to follow the trail of how the new mega-companies came into being.

With Allergan and Pfizer ranking as the biggest-ever pharma merger, per data from Bloomberg, here is a list of the industry's seven largest deals over the past 15 or so years.

1. Allergan announces merger with Pfizer in an all-stock deal valued at \$160 billion

Top 15 Pharma Companies in 2001

1. Pfizer
2. GlaxoSmithKline
3. Merck
4. AstraZenca
5. Bristol-Myers Squibb
6. Aventis
7. Johnson & Johnson
8. Novartis
9. Pharmacia
10. Lilly
11. Wyeth
12. Roche
13. Schering-Plough
14. Abbott Laboratories
15. Takeda

Top 15 Pharma Companies in 2015

1. Johnson & Johnson
2. Novartis
3. Roche
4. Pfizer
5. Sanofi
6. Merck
7. GlaxoSmithKline
8. AstraZeneca
9. Bayer
10. Gilead Sciences
11. Teva
12. Amgen
13. AbbVie
14. Lilly
15. Bristol-Myers Squibb

2. Pfizer acquires Warner-Lambert in 1999 in an all-stock deal valued at \$87.3 billion
3. Sanofi buys Aventis SA for \$73.5 billion in 2004 in a cash and stock deal
4. Glaxo acquires SmithKline Beecham for \$72.4 billion in stock in early 2000
5. Allergan acquires Actavis for \$65 billion, in a cash and stock merger that closed in 2015

6. Pfizer acquires Pharmacia for \$64.3 billion in stock in 2002
7. Pfizer acquires Wyeth for \$64.2 billion in cash and stock in 2009



PATRICK LINDSAY
President, UBC

Despite ongoing M&A, the number of pharma companies has increased substantially, especially among those companies with just one or a few products in the pipeline. The number of products being approved is increasing, as well as the range of therapeutic areas served. While there is always criticism of pharma, tremendous excitement has been building in our industry. Regardless of size, companies that will leave a lasting legacy in this industry are those willing to build on that excitement in a positive way, drive innovation, and ensure the highest quality of patient care.



SHERRY FOX
President, North America
The Planning Shop
International

The biggest change I have observed over the last 15 years is the trend in mergers, acquisitions, and partnering, both among

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pharma and biotech manufacturers, as well as among research and communications agencies. As a result, we all need to be savvy connectors, whether brokering an acquisition deal or finding partnership opportunities to add value for clients. The new year promises to be as exciting as ever and I look forward to being a part of it.



BOB FINKEL
CEO/Lead Strategist,
FreshBlood Health Market
Consultants

The product pipeline race forces many established biopharma companies to look outside of internal R&D for tomorrow's therapies and in-licensing opportunities. Biopharma start-ups are springing up like never before, having become a popular feeding ground for those in search of inno-

vation. Mergers and acquisitions are today's norm. Due to this constantly shifting corporate landscape, the classic advertising agency model is becoming obsolete because of forced consolidation.



JACK FLORIO
Partner, Strategy
Consultant
Deallus Consulting

Strategy remains a long-term initiative for companies, but it has become more dynamic in the short term. The rapidity of change, including M&A, partnerships in both clinical trials and commercial, patient and payer impact in decision making, etc. have caused strategy to be a living activity. Strategy must include an ongoing environmental and competitive focus, utilization of tools such as real-time game theory modeling, and the ability to monitor

milestones, and know how and when to adapt the living organism of today's strategy.



THOMAS ZODA, PH.D.
Executive VP and
General Manager, Clinical
Development, CNS
INC Research

The continued consolidation of the industry, and the move of many large pharma companies to shift from internal development to acquisition of assets and small companies to build their profiles has shifted the outsourcing model. Dependence on CROs has grown, and there continues to be shift from more tactical to strategic relationships. Tailoring service to need, with different approaches for large pharma versus small biotech, will be crucial for CRO success, as well as being able to deliver quality talent in a tightening labor pool.

► Global Markets

More than half of the world's population will live in countries where medicine use will exceed one dose per person per day by 2020, up from 31% in 2005, as the "medicine use gap" between developed and pharmerging markets narrows. According to new research released by the IMS Institute for Healthcare Informatics, total spending on medicines will reach \$1.4 trillion by 2020 due to greater patient access to chronic disease treatments and breakthrough innovations in drug therapies. Global spending is forecast to grow at a 4% to 7% compound annual rate over the next five years.

In 2001, the focus was on BRIC nations, a term that was also coined that same year by Jim O'Neill from investment bank Goldman Sachs in a paper titled "Building Better Global Economic BRICs." BRIC stands for Brazil, Russia, India, and China. Today, the acronym has come into widespread use as a symbol of the apparent shift in global economic power away from the developed G7 economies toward the developing world.

Projections on the future power of the BRIC economies vary widely. Some sources suggest that they might overtake the G7 economies by 2027. More modestly, Goldman Sachs has argued that, although the four BRIC countries are developing rapidly, it would only be by 2050 that their combined economies could eclipse the combined economies of the current richest countries of the world.

In an interesting twist, in November 2015, Goldman Sachs shut down its BRIC investment fund, merging the more than \$100

billion in assets-under-management fund with a larger emerging market one, which marks what Bloomberg calls "the end of an era."

According to a paper published in 2005, Mexico and South Korea were the only other countries comparable to the BRICs, but their economies were excluded initially because they were considered already more developed, as they were already members of the OECD. Mr. O'Neill also endorsed the term MINT, which includes Mexico, Indonesia, Nigeria, and Turkey.

Over the years, investor attention has shifted from emerging markets to "frontier markets," a classification made up of economies smaller than those of the BRICs.



DR. MIREILLE GILLINGS
President, CEO, and
Executive Chairman,
HUYA Bioscience
International

An important trend gaining momentum is the expansion of Asia-Pacific pharmaceutical markets and their underlying research investment. Life-sciences innovation in China is attracting capital investment in both public and private markets. One example is cancer immunotherapy that promises to harness the immune system to destroy tumor cells. HUYA Bioscience International is advancing this trend with its China-sourced cancer drug, HBI-8000, under development globally. This is the first oral histone deacetylase (HDAC) inhibitor that has

the additional advantage of immunomodulatory effects. HUYA is the pioneer in leveraging the Tripartite Cooperation Treaty between China, Japan, and South Korea, enabling an acceleration of development of HBI-8000 in Asia for both liquid and solid tumors.



DR. MARLENE LLOPIZ
President,
Association of Medical
Specialists in the
Pharmaceutical Industry/
President Mexican
Chapter ACRP

The pharmaceutical industry has undergone a tremendous transformation in the past 15 or so years. As a two-time president of the Association of Medical Specialists in the Pharmaceutical Industry (AMEIFAC) in Mexico and with more than 20 years working at CROs and pharmaceutical companies, Latin America (LATAM) has shown to be a "hub" for clinical trials and the marketing of diverse drugs. I have seen generics come into play heavily and now biotechnology drugs coming on board. It is important to have the world know that Mexico is a major source for marketing important drugs for therapeutic indications such as oncology, endocrinology (diabetes), heart disease, and neurological problems. Mexico is the door for entering into LATAM and should continue to be in the limelight for all pharmaceutical and biotech companies to market their drugs.

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