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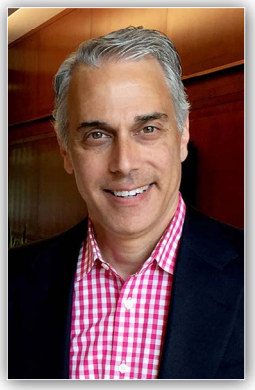
By Taren Grom

Trending 2018: What Does the Future Hold?

Industry experts representing varied disciplines identify the trends — from accountability to wearables — they think will impact the business of the life-sciences in the coming year.

We tasked the PharmaVOICE 100 community of industry executives to think about some of the most important trends they expect will challenge the status quo, move the industry forward, and contribute to breakthroughs in medicine and business models. Their thoughtful insights signal the multitude of challenges and opportunities that lie ahead in the coming year.

Accountability



DAVID PARAGAMIAN
Managing Director, Razorfish Health
PharmaVOICE 100 honoree — 2017

The key issues for the industry in the next year can be summed up in three words: accountability, science, and risk.

The watchword is accountability across the board. The industry as a whole is acknowledging, somewhat reluctantly, that we are accountable not only to federal regulatory bodies, but the general public. How we market our products, how we price our products, and how we behave matters. And, pharma companies will continue to demand more accountability from service partners, such as ad and communications agencies. Metrics and results matter.

In an industry under attack, having a molecule that works differently — really, really works and provides a strong value prop to physicians, patients, and payers — is everything. Companies, both large and small, that focus on the disease and a deeper understanding of the science bringing novel mechanisms and approaches to bear to help control or mediate that disease will be rewarded vs. the purely marketing-driven product with me-too science.

We see successful pharma companies taking risks to embrace the social media channels and the power of the patient and advocacy communities. We see successful pharma companies breaking with the past to install new leaders not from the traditional commercial function. Similarly, service providers will be most successful where they can break from past approaches that are the time-worn traditional paths. Big, bold thinking will produce growth and business building ideas.

Rare Disease

LISA BOYETTE, M.D., PH.D.
Co-Founder and CEO,
Curable
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PharmaVOICE 100
honoree — 2016

The biggest trend impacting rare disease discovery and drug development work for 2018 will be cross-disciplinary, multi-sector collaborations. We are finding it is increasingly easy to convince stakeholders around rare disease to collaborate with other types of stakeholders. This includes drug developers, academics, government, patient communities, payers, and others. In the rare disease world, it takes participants from every sector working in tandem to make the most of small patient populations, precious samples, and tight timelines for delivery in the absence of effective treatments.

Regulatory Changes

JANE WINTER
Senior VP, Head of Regulatory & Quality Consulting,
inVentiv Health Consulting, part of INC Research/inVentiv Health
PharmaVOICE 100 honoree — 2017

Now and in the future, regulatory changes will impact how pharmaceutical companies handle their quality compliance framework for drug development. It's no secret that the ever-changing regulatory environment presents challenges for organizations with the potential to impact enterprise value, if significant compliance issues arise.

To name a few, the global regulatory environment has seen the implementation of the updated ICH GCP E6 (R2) this year and the planned introduction of the General Data Protection Regulation (EU2016/679) in May 2018 as well as the EU Clinical Trial Regulation (EU 536/2014) in 2019. These compliance updates will signal significant changes for organizations: assessment and redesign of operating models, revising roles and responsibilities, implementing more stringent approaches and documentation regarding vendor oversight, and making changes to data handling and storage processes and integrated Quality Risk Management Systems (QMS).

Consequently, potential noncompliance with new legislation could damage the overall product value through delays in product development and license approval possibly could reduce the ability to find optimal licensing opportunities. In some extreme cases (e.g., noncompliance with the GDPR) this could result in fines up to 2% of global turnover. Ultimately, CEOs are held accountable for their organization's compliance, which is why fostering a robust QMS in a challenging regulatory environment is so crucial.

For start-up companies with limited resources engaging in product development, the need for compliance is especially pressing. However, investing early on in a robust QMS protects assets and ensures a compliant framework moving forward. Future growth hinges on understanding and adherence with regulatory expectations — increasing the potential value of an asset to investors or development partners.

ALEX ZAPESOCHNY
President and CEO,
iCardiac Technologies
PharmaVOICE 100
honoree — 2016

The landmark regulatory revision adopted by the International Council for Harmonization in December 2015 represented the most significant shift in the cardiac safety field in over a decade. The revision defined an alternative path to having to do a costly, stand-alone thorough QT (TQT) study by enabling sponsors to assess cardiac safety much earlier in the development process using ECG data from routine Phase I studies.

This regulatory action unleashed a flurry of activity among sponsors, clinical sites, and cardiac safety vendors as they sought to implement the new method into their operations and development plans. In the last two years, dozens of pharma companies have used this approach, and many other pharma companies have piloted it as a precursor to applying it across all their development programs.

The experience of these early adopters has been extremely compelling. Not only are they forgoing the multimillion-dollar cost of conducting a TQT study, they are also discovering the other benefits that come with this approach, including getting critical cardiac safety data as much as years earlier in the development process. For instance, getting this data during Phase I provides smaller pharma more leverage in partnership or investment discussions as they look to move a compound forward.

We believe that 2018 will be the first year during which a majority of drug developers will begin choosing this alternate path rather than doing TQT studies. This would be a welcome and beneficial trend indeed.

Risk-Based Monitoring

SUSAN ATKINSON
Senior VP, PPD
PharmaVOICE
100 honoree —
2017

During 2018, ICH E6 R2 is going to be in full force, impacting how pharma companies, their

vendors, and CRO partners address the topic of risk-based monitoring. The intent of the guideline revision encourages and enhances a risk-based approach to trial execution and related quality management aspects.

Within the framework of this guidance, there are many successful ways to accomplish improving data quality and increasing appropriate oversight.

Avoiding distractions and keeping the reasons behind this revision clearly in focus allow clinical trial professionals to use data to evaluate quality limits, assess root causes, and look for patterns in data to drive decisions. The availability of analytical techniques and increased abilities to integrate and store data align well in support of this directive.

Early and cautious adopters will work to understand the gap between current monitoring to include risk-based and centralized monitoring. Industry consortiums will seek to bring clarity in vocabulary and intent. A fit-for-purpose mindset will be necessary to create a balance among traditional monitoring, remote monitoring and centralized analysis techniques. The companies that do this best will be those that lead their organizations through change while keeping the core data and quality premises top of mind.

PATRICK HUGHES
Chief Commercial Officer,
CluePoints
PharmaVOICE 100
honoree — 2015

The adoption of risk-based monitoring (RBM) has come of age across pharma companies and CROs, driven by a combination of the desire to improve operational outcomes and emerging regulatory guidance, including the recent ICH E6 (R2) addendum. Embracing risk-based approaches, although still in its infancy, is enabling companies to see where future opportunities exist, with machine learning and predictive analytics emerging as important pieces of the jigsaw.

While the industry has taken great strides when it comes to robust and comprehensive analytics to pinpoint atypical data patterns representing operational risk, it is still down to central monitors (CMs) and clinical research associates (CRAs) to review those anomalies and make decisions on the right course of action, including the decision not to act. Machine learning uses algorithms and decision support models to look at how issues have been successfully corrected in the past, providing guidance on resolutions that will produce the correct result. With so many RBM initiatives under way, machine learning will bring much needed consistency to the process. It holds the potential to harmonize and streamline all decisions made across an organization, and across different organizations to promote a common industry approach.

As pharma becomes increasingly immersed in RBM, there will also be a greater desire to be able to anticipate where potential problems lie. Predictive analytics uses historic clinical data sets and results from past trials to provide insight into likely outcomes. This means that patterns can be identified that could develop in the future, paving the way to greater oversight, higher quality data and safer trials.

Machine learning and predictive analytics represent the start of another major change for the industry. Smarter systems mean smarter, faster, more efficient decisions and the potential to harness more knowledge will ensure the best results for patients and sponsors.

Social Media

NATALIE MCDONALD
President and Founder,
Create NYC
PharmaVOICE 100 honoree — 2017

In 2018, we will see social media continue to be a platform where consumers spend most of their online time and even more pharmaceutical brands will explore this channel. Facebook will continue to be the prime destination for optimal engagement with consumers. The platform allows for immersive content to increase awareness, drive engagement, and convert. In addition, precise targeting via data analytics will help ensure the right messages go to the right consumers on these platforms. By incorporating operational platforms for social media, a strategic execution agency will be able to compliantly and efficiently scale these programs across an organization with incredible speed to market.

Wearables

STEPHANIE DEVITERI
Managing Director,
Tonic
PharmaVOICE 100
honoree — 2017

A major trend that healthcare companies will continue to navigate — and be forced to embrace — is the rising consumer demand for predictive and self-diagnostic technology that monitor vitals, habits, and symptoms to diagnose the presence of potentially serious diseases. According to the International Data Corporation (IDC) Worldwide Quarterly Wearable Device Tracker, the worldwide wearables market grew by slightly more than 10% in second-quarter 2017, with shipments of the Apple Watch increasing by almost 50% from 2016 to 2017. Perhaps this is why it came as no surprise when Apple recently announced its partnership with Stanford University for the Apple Heart Study. Researchers hope to use Apple Watch data to help detect abnormalities in heart rate and heart rhythms that may otherwise go undetected. Wearables not only build community and support networks, for example, especially among those of us who like to compete against friends to log the most steps over a weekend, they collect real-time data to monitor conditions and even track improvement of symptoms with treatment intervention. While smartwatches are far from replacing a visit to the doctor, they are well-positioned to dramatically change the way we manage our health if manufacturers can effectively address regulatory hurdles.

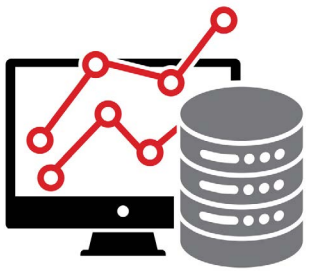
Behavioral Economics

BRUCE FEINBERG, DO
VP and Chief Medical Officer,
Cardinal Health Specialty Solutions
PharmaVOICE 100 honoree — 2015

In 1987, I was two weeks out from my MD Anderson fellowship and attending my first hospital tumor board as a solo private practice community oncologist. The first case was a young woman with Hodgkin's disease; the presenting physician was a similarly young oncologist in his third year of private practice. His presentation was crisp but his conclusion to treat the patient with a non-standard regimen drew my curiosity, I raised my hand. He explained that his first Hodgkin's patient in private practice died of a rare adverse event to one of the drugs in the standard regimen and he was using this non-standard treatment to avoid a similar fate for this patient. At the time I wasn't familiar with the work of Thaler, Kahneman, and Tversky, nor was the field of behavioral economics formally birthed; I was nonetheless witnessing the irrational behavior that is now well explained by the theory. The doctor's experience had injected a bias in his thinking, which prevented him from rational thinking and evidence-based medicine — he would choose to prescribe an inferior treatment than risk a complication that was highly improbable. The myriad factors that weigh on physician prescribing behavior for complex, disabling, and potentially life-threatening diseases like cancer, multiple sclerosis, Crohn's, and a host of inflammatory and infectious diseases, as well as those factors impacting the patients receiving the treatment, eclipse the most sophisticated of behavioral economic modeling. Behavioral economics in medicine explains why computers may be more accurate in radiologic diagnoses, why physicians deviate from evidence-based medicine, why patients may be non-compliant with life-sustaining treatments, and why the speculated impact of healthcare delivery reform may be overestimated. Economic Darwinists take heed: the bedrock on which much of reimbursement reform is founded assumes rational economic behavior. In 2018, behavioral economics may be the trend that turns that assumption on its head.

Big Data

SY PRETORIUS, M.D.
Senior VP & Chief Scientific Officer,
Parexel
PharmaVOICE 100 honoree — 2017



Today in healthcare, we have access to an ocean of data. In 2018, the volume of data will only grow due to, among other things, meaningful use of electronic health records, expanded use and adoption of wearable sensors, increased use and understanding of genomics, and the rise of artificial intelligence. However, with access to so much data at our fingertips, the key question will be how do we derive insights and value from this data?

The answer lies in getting access to the right data, analyzed in the right way, in the hands of the right people to drive predictive and preventive actions. The effective use of this data can better inform design, start-up, execution, submission, and commercialization.

I anticipate — and believe — that, as an industry, we'll make further significant strides in leveraging data in 2018 and that this will enable us to help bring drugs to market effectively and efficiently, with the ultimate goal of bringing more safe and effective treatments to patients.

JOHANNA SKILLING
Head of Planning,
Ogilvy CommonHealth Worldwide, a WPP Health & Wellness company
PharmaVOICE 100 honoree — 2017

Zeros and ones versus neurons and hormones. The rise of the robots. The supremacy of data. Our current buzzwords — data, VR, AI — sometimes seem like they're elevated beyond human action. But we all know that they're simply tools — invented by us, for use by us. Unless you're in the same camp as Elon Musk, and you're legitimately worried about our future AI overlords. Our challenge is to apply human ingenuity and human creativity to the opportunities created by coders. We have the ability to collate vast amounts of information and the ability to connect billions of people, in personal conversations that go beyond any antiquated notion of segmentation. So our challenge is to navigate how information — the bits and bytes that increasingly capture every nuance of our behavior, and increasingly, our feelings — can be put to work in service of human needs. How do we generate meaningful insights from database reports and dashboards? How do we know what creates conversation, attraction, loyalty?

On the flip side, how do we use big data creatively and thoughtfully to better understand our customers, our stakeholders, and the world they live in? How can we use AI to create more fulfilling experiences for the people who use, recommend and pay for our products?

We can think big. Now more than ever, we can use the tools at hand to change lives for the better. We can do better than simply turning to machinery to create new opportunities for our brands and businesses. Let's put our ingenuity to work in terms of how we use them creatively, strategically, and courageously to bring healthcare to people in ways we can now only dream of.

Blockchain

WILLIAM KING
Founder,
Zephyr Health
@Zephyrhealth
PharmaVOICE 100
honoree — 2016

The year 2018 will bring about a paramount shift in how data are stored and accessed. With the recent data breaches from Equifax and Yahoo, which affected nearly every American, data security concerns have risen to a crescendo. Data privacy is on everyone's mind, but when it comes to healthcare, the allure of a secure cryptographic data-storage solution applied to healthcare systems is too important to ignore and technologies such as blockchain could revolutionize the way healthcare systems think about data. By dispersing data into secure "blocks," rather than storing in traditional centralized systems, each point will have a complete record for its block, making it impossible to tamper with all the data as a whole. In addition, the secure nature of blockchain technology would allow individuals to access and modify their own unique strings, and, for the first time all stakeholders could be assigned a single-personal record and have a say about where and when those records are shared. Finally, blockchain technology could offer the solution of a universally accessible network of data that remains secure but provides value to all stakeholders: patients, clinicians, and researchers. As data and healthcare systems continue to integrate and connect the dots, solutions powered by blockchain technology might quickly take their rightful places as the next natural step in big data in healthcare.

Clinical Technology

BILL BYROM, PH.D.
Senior Director of Product Innovation,
ICON
PharmaVOICE 100 honoree — 2008, 2017

The number of trials using electronic approaches to collect patient-reported outcomes (PRO) data continues to grow, driven by the improvement in the integrity, quality, and timeliness of data collected and increased data visibility.

However, perceived barriers continue to exist, not least in the production of evidence to support the measurement equivalence of instruments migrated from paper to electronic forms. This perceived barrier is raised further when considering patient-centric designs that leverage the patient's own mobile device to collect ePRO data — bring your own device or BYOD — as the variety of screen shapes and sizes may be great.

It has been eight years since the publication of the ISPOR ePRO Good Research Practices Task Force recommendations on the evidence needed to support measurement equivalence when migrating from paper to electronic formats. This task force recommended that minor changes to an instrument due to migration should require a cognitive interview and usability testing (CI/UT) study in the target patient population to demonstrate measurement equivalence. Since then, our industry has conducted many such studies to provide supporting evidence of PRO suitability for regulatory submissions. We recently conducted a qualitative synthesis of all CI/UT studies conducted by ICON between 2012 and 2015 comprising 101 instrument comparisons. Our analysis provides strong evidence to support the generalizability of migration equivalence of instruments when important aspects of ePRO design best practice is followed.

Importantly, we have since completed the industry's first formal quantitative equivalence study examining the measurement properties of instruments delivered using BYOD, a standard device, and paper. This provides valuable evidence to support the BYOD approach when design best practice is followed during the migration process.

We believe that 2018 will be an important year in turning the tide toward the use of BYOD and simplifying the use of ePRO.

ELISA CASCADE
Chief Product Officer,
DrugDev, a QuintilesIMS company
PharmaVOICE 100
honoree — 2016

While working in R&D technology, my goal is to strive for win-win solutions that both improve efficiency for pharmaceutical companies/CROs and decrease site burden. One such technology, online profiles, is a good example. Sites can enter information about themselves and their facility once and have this data support a number of activities such as site selection, feasibility, and start-up. By sharing standard information, sites should be able to focus on protocol-specific questions, rather than providing the same basic information over and over again.

Sites know the benefits of online profiles; indeed, approximately 80% maintain at least one, according to our 2016 global survey of 418 investigators across eight countries. With the lack of an industrywide solution, however, many sites maintain multiple profiles with 35% reporting three-plus profiles, and almost 10% maintaining 11 or more.

I don't underestimate what it will take to achieve a single online profile. We need industrywide acceptance that investigator information is not proprietary. Then we require standardization on the profiles content, and although TransCelerate has put forth some guidance, many pharmaceutical companies/CROs still maintain their own version. Finally, and likely most challenging, is the need for everyone to agree on a unified consent process, and a provider that can facilitate industrywide sharing of profiles data. While the road ahead is difficult, it's worth it. I strongly believe it is within our grasp to reduce the burden for sites and embrace allowing sites to give information once, and share with many.

DONALD DEIESO, PH.D.
Chairman and CEO
WIRB-Copernicus Group,
PharmaVOICE 100
honoree — 2016

Although we are often slow to embrace it, technology continues to transform the biopharmaceutical development industry. Each decade, new technologies allow us to externalize more of

our human abilities, making us more efficient and more productive. In the 1970s and 1980s, our calculating abilities increased dramatically with the advent of the first computers and microprocessors. In the 1990s and 2000s, our ability to communicate increased as we connected the world through vast networks, such as the Internet. And in the 2010s, we created machines and algorithms capable of organizing massive amounts of data, analyzing patterns in that data, and using that analysis to advise appropriate action.

Today, artificial intelligence is successfully being used to augment human judgment. In clinical trials, we are seeing powerful results with the adoption of decision support technologies. From helping to predict which investigator sites are likely to enroll the most patients, to identifying the best channels for patient recruitment, designing the least burdensome contracting processes and facilitating the digital distribution of study materials, artificial intelligence is helping us to make better, faster decisions.

In the next decade, big data will yield to big analysis. Gathering information will no longer be as important as how we use it. In 2018, the most successful organizations will be those that harness the power of this new technology to improve decision-making and drive greater efficiency.

ERIC DELENTE
President, Patient Consent,
DrugDev, a QuintilesIMS company
PharmaVOICE 100 honoree — 2017

Right now, more and more sponsors are starting to recognize the benefits of eConsent, and are adopting it in record numbers. The benefits of the technology itself have started to become clearer, and we're losing some of the mysticism that surrounded eConsent because sponsors, sites, and patients are seeing that it works. Early adopters have used it on small and large trials, and others are seeing that patients and sites want it.

Much like any new clinical trial technology, people were skeptical of change and eConsent's ability to improve patient engagement and retention. Practitioners had heard the rhetoric but were reluctant, wondering if eConsent would work on global studies with different country regulations and regulatory bodies, different languages and customs. But as early adopters completed trials using eConsent, data on positive outcomes changed attitudes, and we're arguably at peak bell curve in terms of sponsor, CRO, and industrywide demand.

As we enter 2018, eConsent finally will begin to be seen as standard practice. And that's fantastic, because we should always be looking to adopt anything that makes clinical trials easier for patients and sites.

MELISSA EASY
Global Head, Strategic Accounts,
DrugDev, a QuintilesIMS company
PharmaVOICE 100 honoree — 2015

Recently we've seen a shift toward sponsors wanting to implement a single technology platform that spans every trial function across multiple studies. After years of inundating sites with a different system for each activity and a different password for each one, the industry is seeing the benefits of a single, flexible system — one that works on any device, and handles all site facing functions.

It had become commonplace to expect sites to log into a different system for each component of the trial: one for feasibility, another for activation, another for document management, another for training, another for trial engagement, another for payments and so on. It makes little sense as it requires an inordinate amount of costs and administrative tasks to manage all of this technology, hoping they will all talk to each other and make it easier and more efficient to run trials. Why run a 100-meter dash using the relay format, and risk fumbling the handoff, when you can just use a single runner?

As we move toward the future we're going to see more and more companies select a single unified technology platform for all their studies across the board. A single platform reduces the amount of administrative burden on sites, is simpler, reduces the time investigators, CROs and sponsor study teams must spend learning systems, and ultimately improves efficiency and timelines for trials. That's great for not only sites, but for the entire industry.

NICOLE HEBBERT
VP, Patient Access & Engagement,
UBC
PharmaVOICE 100 honoree — 2016

Speed to therapy will get faster. New, dynamic technologies will improve access to treatment by removing burdens on prescribers, payers, and patients. Increasingly, manual processes are being replaced with a single click that can set patient-support services in motion — from investigation to adherence management. The pressure is on us and our industry to create more connected care by standardizing information sharing across electronic medical records and other healthcare and pharmacy databases. We'll continue to improve on this process, allowing patients to have a continuum of care, tailored to their healthcare needs, as well as personal preferences.

IBS MAHMOOD
Head, Clinical Technology Business,
DrugDev, a QuintilesIMS company
PharmaVOICE 100 honoree — 2014

It's become rather a tired mantra to say pharma will never change. Based on the many conversations I have every day with leaders of major pharmaceutical companies, I truly believe that we'll start to see real changes in the way we run clinical trials — and real results from these changes — in 2018. Unlike in the past, innovators understand they're not risking their careers or the bottom line by using technology to run trials. In fact, I believe the "do we need unified technology" debate is over. The people in charge know they need

to use technology that establishes standards, enables collaboration, and provides a beautiful experience for sites and study teams. The next trend will not be implementing technology on one or two clinical trials each year, but on all of them. At DrugDev we call them enterprise deployments, and they are already happening at some of the world's biggest companies.

We automate so many aspects of our lives we don't even pause to think about it anymore. I expect the same thing will happen in pharma. We'll see an exponential growth in the number of sponsors and CROs that are using the same system to share data and manage operations with real-time transparency. Thankfully, I'm proud to say we're past the point of debating whether such technology is necessary. Now we get to see just how ubiquitous it becomes. I'm excited to see where this groundswell will take clinical research in 2018 and beyond.

KENT THOELKE
Executive VP, Scientific and Medical Affairs, Safety and Commercialization Services,
PRA Health Services
PharmaVOICE 100 honoree — 2013

The drug development industry is at a crossroads, and the next few years will see an incredible amount of long overdue, positive disruption, resulting in broader patient engagement and quicker time to market for many new therapies. For the last 20-plus years industries outside of drug development have seized on advancements in technology to propel efficiencies and consumer access forward at speeds exponentially faster than in previous decades. The ability to take new technology and adapt it quickly has proven successful in consumer, financial, and manufacturing industries. Drug development has not kept pace. However, as pricing pressures mount on pharma and biotech, the need for the adoption of novel and innovative technologies to help decrease development costs will no longer be a luxury but a necessity. A key growth area for 2018 will be finding improvements in how the industry engages with patients as consumers, and integrating how we connect with those patients via technology used in their everyday lives. By leveraging existing technology and applying it to the clinical development process, we will improve access to clinical studies, increase patient participation, and decrease overall timelines to move new therapies through the approval process — and ultimately on to the patients who need them.

RACHAEL WYLLIE
CEO,
CRF Health
PharmaVOICE 100
honoree — 2015

Innovations, such as Bring Your Own Device (BYOD), reflect an exciting era for clinical trials, with Web and app-based solutions changing the way patients engage with technology. Patients are becoming more engaged in their own health and the prevalence of personal technology, which allows patients to monitor their own health, makes for ever more engaged patients in the clinical trial landscape.

The use of continuous monitoring, for instance glucose monitoring, offers new possibilities for data collection, however the challenge remains on what is regulatory acceptable and how to reliably use the plethora of data generated. There's growing interest in giving data back to patients so they understand the context of their participation, and although there are some good examples of this it remains far from being incorporated into trials as standard.

Given the multitude of ways in which data are collected, it is encouraging to see data quality remaining high, certainly many times higher than traditional paper-based methods, and feedback from patients, caregivers, and physicians remains equally positive. We continue to see a trend toward increasing patient and site compliance via eCOA solutions. Increased regulatory scrutiny of eCOA data has been a recent development suggesting the digital collection of these data is now largely considered mainstream.

Patient engagement always remains a hot topic — the trend of not treating patients like guinea pigs but as active participants in the trial needs to continue, with consideration given to both subjective and objective measures. There is still work to be done to simplify the process, and in my experience the simpler the solution, the better the data, the more engaged the patient.

Collaboration

JOE DEPINTO
President,
Cardinal Health Specialty Solutions
PharmaVOICE 100 honoree — 2017

The trend that will most impact the healthcare industry in 2018 is growing complexity across all aspects of drug development, commercialization, reimbursement, and care management, which will lead to an increased need for collaboration among healthcare stakeholders. As an example, in complex specialty and rare disease states, we are seeing collaboration in clinical development where two or more companies are working together on trial design and providing drugs for investigator-initiated trials, cooperative group trials, and even co-manufacturer sponsored trials. The hope is that these collaborative clinical initiatives will result in greater innovation and improved care for patients. We are also seeing increased collaboration in the reimbursement space where manufacturers, providers, and payers are working together on value-based agreements where the stakeholders have shared accountability for ensuring patients achieve optimal outcomes. In 2018, we will continue to see increased collaboration across all areas of life sciences — and the most effective partnerships will be those characterized by a shared commitment to goals, deliverables, and timelines.

MICHAEL MURPHY, M.D., PH.D.
Chief Medical and Scientific Officer, Worldwide Clinical Trials
PharmaVOICE 100 honoree — 2017

Unprecedented developments within discovery research suggest that 2018 will bring an accelerated shift toward strategic sponsor-CRO relationships along the discovery/development continuum. The impetus for strategic versus transactional relationships parallels product innovation and the emerging complexity within clinical trial environment that must facilitate commercialization in a payer-centric market, in which differentiation on value as well as therapeutic novelty is mandated.

Repurposed products and novel chemical or biological entities require proficiency with established, as well as innovative, clinical development programs. Although there is portfolio value in recapitulating predictable development pathways, increasing emphasis for a therapeutic neighbors strategy may be observed in 2018 in which a common pharmacological target across multiple indications is initially evaluated, followed by an accelerated development timeline for a specific indication. A mosaic of clinical development options extracted from experiences across multiple therapeutic areas becomes an invaluable asset in this setting, while predictable development to inflection points continues to be a key corporate differentiator.

At the same time, we will see a continued push toward demonstrating evidence-based value during development; i.e., as a component of the registration process, rather than post-approval positioning. Capturing the impact of innovative therapy on a system of care will support provider adoption, payer coverage, and premium pricing, which will result in optimal payment and market access.

In this complex and demanding environment, sponsors placing a premium on the differentiation afforded by the partnering process employed during clinical development will maximize portfolio value. CROs with experience, vision, and a commitment to provide sustained, differentiated services will add considerably to portfolio value.

ALEXANDRA VON PLATO
Global Group President, Communications & Media, Publicis Health
PharmaVOICE 100 honoree — 2013

Partnerability is the new essential capability. While there's no denying that healthcare is going through an era of rapid and tremendous change, industry keywords like disruption and transformation seem to be losing their meanings. Change is inevitable, but how we confront change is not. The key to effectively navigating through massive change is knowing what you know and knowing what you don't know.

As such, partnerability increasingly will become a critical organizational capability for any company operating in the healthcare space. At the ever-accelerating pace of change in this business, no single company will be able to adapt and keep up. Therefore, the ability to smartly partner with an ever-wider and even more diverse set of players and partners, including startups, technology platforms, and content creators, both quickly and effectively will become a key competitive advantage for healthcare marketers, agencies, and consultancies. The need to identify and drive the right connections quickly and create win-wins that attract the best minds will upend the current procurement-driven approach to vendor management that many of us in the healthcare communications business grapple with every day. Fast, big ideas developed by new, surprising, and often strange bedfellows will become a best practice for the most successful companies.

Digital Transformation

UBAVKA DENOBLE, M.D.
Corporate VP, Patient Technology Solutions, Parexel
PharmaVOICE 100 honoree — 2016

In 2018, we are well on the way to seeing the digital transformation of our industry. We understand that by embracing technology, we can improve productivity, compress development cycles, and cut costs. This can only come about by delivering leading technology paired with optimized trial design.

Patient-centricity will be a key focus of trial design and technology going forward. We will see increased access to patient-reported data as wearables are integrated into trials. The potential of this technology development is unlimited, and it holds great promise in transforming the clinical trial process by not just improving the patient experience and eliminating the burden on sites and their staff, but in ultimately providing sponsors a deeper level of data and insights.

ANDY PYFER
Partner, Fingerpaint
PharmaVOICE 100 honoree — 2015

The trend that will continue to impact the industry in a meaningful way is the idea of media as the new "creative." The notion that media should have a seat at the table during the creative process is becoming undeniable. Developing campaign ideas without first thinking about where and how you plan to engage customers in today's primarily digital marketing landscape could be seen as negligent. As marketers, it's essential we recognize that our brand typically isn't the center of our customers' world. In fact, we have but a fraction of time to influence them. If we combine this understanding with an informed media plan, we can develop campaigns and content that not only captivate and inspire, but also hit home in those "micro moments." Hermeti Balarin, executive creative director at Mother London, explained it simply, yet beautifully, at Cannes this year: "We put the opportunity in the middle and collaborate." Moving forward, it will be hard to imagine media not playing a leading role in the creative process.

Expanded Solutions

LANCE SCOTT
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PharmaVOICE 100
honoree — 2017

Data and analytics will play a central role in the healthcare industry's pursuit of moving beyond the pill, especially as more and more life-sciences companies continue to take the expanded solutions approach across the continuum of care, which includes product and services. The vast number of digital data points around customer engagement will be more regularly integrated into go-to market strategies. Augmented intelligence and machine learning will play a prominent role in this by parsing, linking, and connecting this data so that it can be a living, breathing feedback mechanism for improvement in delivery. We will also see life-sciences companies using data to work through the increasingly complex stakeholder environment that now includes physicians, patients, networks, payers, and regulators. Not all companies will break through this dynamic, though. Those that do will leverage data in a way that provides actionable insights necessary to apply the right resources, at the right time, to implement the most effective go-to market strategy. In due time, meaningful and predictive insights will be the universal language that life-sciences companies use to take a more holistic approach to the patient journey, unite their stakeholders, and provide solutions-based treatments.

Gender Parity

NICK COLUCCI
Chairman and CEO,
Publicis Health
PharmaVOICE Red Jacket
Honoree — 2014

When it comes to having honest, open conversations about discrimination in the workplace, there is no better time than now to shine a light on destructive behavior and, more importantly, to consider how we should act. Clearly, repugnant discriminatory and bullying behavior in the workplace against women and people of color — more often than not perpetrated by white men in powerful positions — capture headlines, yet it's the daily actions caused by unconscious bias that are much more insidious and difficult to fix. While it's critically important that we are vigilant and continue to bring forward what most all of us know to be odious and unacceptable behavior, it's even more important to understand that unconscious bias is something that we all — as individuals — have, yet very few of us know how to define, spot, or correct. This understanding is particularly critical for those of us with influence and power. After all, if we can't see it nor name it, we can't work toward a solution.

Maya Angelou once said: We allow our ignorance to prevail upon us and make us think we can survive alone, alone in patches, alone in groups, alone in races, even alone in genders. Our inherent biases are informed by what we believe we know and what our experiences and our gut tell us. Add that to the "it's lonely at the top" notion that leaders must make decisions and act alone, and there's a dangerous recipe for destructive prejudicial behavior. When we can learn to identify, acknowledge, understand, and accept our own biases, we naturally become more compassionate toward others. In the coming year, those of us who proudly identify as allies and advocates for gender parity and anti-racism will continue to make our voices heard. Not only by screaming at each other, but by encouraging and inspiring others in positions of influence to embark on a journey of self-discovery, attend training sessions on unconscious bias, and read books like Howard Ross's Everyday Bias. To know others, you must first know yourself.

Innovation and Evolution

TIMMY GARDE
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PharmaVOICE 100 honoree — 2012

Innovation is the biggest trend, period. Augmented, virtual, and mixed reality are going to play a huge role, not just in promotional communications, but in the practice of medicine. Imagine a VR "flight simulator" for surgical residents — that's a powerful teaching tool, and it's going to become indispensable. VR applications can help physicians, nurses, technologists, family caregivers, and patients.

Augmented reality brings the digital world into the physical world in an engaging, almost magical way. People eat this stuff up — look at how Pokemon Go did out of the gate; it had an incredible user base almost overnight. The idea that a design, a bit of copy, an object you find in the real world can be tied to the digital world opens the door to infinite possibilities. AR capability is baked in to the latest iOS release, so Apple is taking it seriously. It's a great way to interact with health content, and

we're urging our clients to consider smart AR tactics in their communications plans to improve health outcomes.

But the real game changer is the emergence of artificial intelligence (AI). Emerging AI technology can process superhuman quantities of data, to give HCPs the most complete picture possible. This means better diagnosis and treatment decisions, and better outcomes. Watch where this goes in the next year.

TERRY HERRING
President, Commercial Operations,
Mission Pharmacal Company
PharmaVOICE Red Jacket honoree — 2017

Continued innovation throughout the pharmaceutical industry is a trend that is clearly impacting how we operate. There is an evolution occurring — some may say revolution — yet the primary driver and really the essence of our job remains unchanged. We are in the business of improving people's lives by cost-effectively providing essential products to patients in need.

There is a way this has been done with varying degrees of success for many years, yet a paradigm shift in how we go about our business is occurring. We need to embrace innovation and make a concerted effort to uncover new and better ways to provide value to the healthcare community. This may mean better products through enhanced development pipelines, exploring alternative distribution options, and striving to uncover greater efficiencies in other areas.

What has worked in the past may not always work in the future. Unfortunately, there can be a tendency for companies and individuals to do just enough to stay "safe." This approach typically leads to complacency and ultimately failure.

ROB PETERS
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MicroMass Communications
PharmaVOICE 100 honoree — 2012

Conservative, inflexible, cautious, circumspect — taken together, these are appropriate definitions for a well-established pharma institution operating in a highly regulated, sensitive environment. But when you look at the other organisms in this environment and see how quickly they are changing, the description takes on a negative connotation and represents an entity at risk of being left behind or becoming irrelevant. That's where pharma is at today. Their customers have changed greatly in the last few years, yet pharma as a whole is too rigid and structured. Frankly, it operates much of the same way it has for the past decade. However, there are some encouraging signs of change, and 2018 may be the year that pharma shakes off the cobwebs and catches up.

The environment already provides plenty of pressure to change. Pharma must continue to adapt in order to flourish. Healthcare and drug pricing concerns are resulting in operational shifts to strategies like value-based pricing and stronger health economics studies. The research shows that it's not so much that consumers want simplified advertising, but rather that the traditional approach does not have the desired effect or may even have a negative effect. Finally, larger pharma organizations have begun to adopt new structures and approaches to better deliver on the real-world needs of patients.

It appears that pharma has begun to shift with the winds of change. Pharma provides patients with novel approaches, and perhaps 2018 is the year that pharma operates with innovation that resembles their products.

FRANK POWERS
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PharmaVOICE 100 honoree — 2011

The creation of new drugs through the synthesis of existing drugs with innovative technologies is becoming a driving force in drug development. On its face, this may sound familiar, but this new kind of synergy between drug and technology is more than just repackaging of a drug into say, a new extended release delivery system. These new drugs are different in that coupling them with revolutionary technology developments are resulting in new therapeutic classes that provide attributes above and beyond those available from the original molecule. It's the advent of innovative technology causing a transformation of existing, approved drugs into completely new options that perform in a way that the original drug never could.

As an example, a new product consisting of a first-generation antipsychotic drug in a device that immediately aerosolizes the compound on inhalation provides rapid absorption into the bloodstream in a fraction of the time compared with previous options. This rapid effect empowers a noninvasive, collaborative treatment approach for psychiatrists that is going to change the treatment of agitation in patients with schizophrenia.

This synthesis is by no means an isolated development. There are more than 20 new entities of this type in development. These entities hold the power and the promise of revolutionizing treatment protocols using this new hybrid of compound and technology. It's a trend that is going to result in literally dozens of new therapies in the next three to five years.

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With approvals of various types of genetic treatments, the brave new worlds of biotech devices and the biggest ROIs in the smallest startups, we are seeing a biotech investment boom at the level of the dot-com revolution. These very real, very significant gains will provide tremendous benefit to patients. The frenzy to ride this gravy train, however, is also bringing out dysfunctional behavior. Watch for some pharma companies to make brilliant alliances, innovations, and breakthroughs, while others try to make any change at all in an effort to appear as brilliant and as innovative.

Our recommendation would be: Do expect to fail, a lot, and don't always aim for positive ROI. But also, do have a long-term plan where you learn from each failure, and you proceed down a path that will result in profit for your company. For example, how will a behavioral modification program be helpful for your product if you are not one of the market leaders? Is your company nimble

enough to take software-as-a-therapy through FDA approval, or do you need to partner with someone with sufficient customer experience design expertise to ensure adherence? There are many opportunities, but good process wins over hype every time.

Marketing Basics

MATT MCNALLY
President Digitas Health North America, Chief Global Media Officer, Publicis Health
PharmaVOICE Red Jacket honoree — 2017

Many marketers are talking about things like big data, VR, AI, and DMPs. These advances are evolving how we approach communications. However, I see 2018 in three simple words, back to basics. It would be an understatement to say healthcare marketing is going through a transformation. However, there is an opportunity to harness this velocity of change into an advantage. Don't over complicate the complex.

Back to basics No. 1 is put the customers at the center of everything you do. If the experience you are creating does not help the healthcare professional or the patient, don't do it. We have gotten into the habit of creating "stuff." If it is taking you weeks, or even months to determine if a piece of content, a media vehicle, or an app will benefit your audience, it probably isn't the right thing to do. Don't be afraid to test new communication strategies or tactics.

Back to basics No. 2 is smaller teams that can make decisions faster. Keep your agency roster small and hold them accountable. Too often, we add bodies to the problem. This simply over complicates things and slows down decisions. Fewer players leaves fewer places to hide and drives ownership.

Back to basics No. 3 is take a media-first approach to marketing. You need to understand how your audiences are engaging with channels and why. Far too often we create content and communications first, without thinking about where they are going to show up. Try something new, brief your media team first.

Molecular Medicine

CHRISTOPHER TOBIAS, PH.D.
President,
Dudnyk
PharmaVOICE 100 honoree — 2012

Twenty years ago, as a biomedical scientist working in gene therapy, I can remember discussions with my colleagues about the fact that there were 10 to 20 times as many articles touting the promise of molecular medicine as there was primary research that actually proved that molecular medicine can work in disease models — let alone dream of someday seeing the benefits in the clinic. Incredibly, today we are witnessing major advancements in molecular medicine in clinical trials and, finally, in the form of FDA-approved treatments for diseases that previously meant bleak long-term outcomes for patients. To highlight just a few over the last two years, the FDA has approved a gene therapy treatment for refractory acute lymphoblastic leukemia (Kymriah, Novartis), an exon-skipping therapy for Duchenne muscular dystrophy (Exondyx 51, Sarepta Therapeutics), and an antisense oligonucleotide therapy for spinal muscle atrophy (Spinraza, Biogen). This harnessing of molecular mechanisms, or genetically modifying cells to combat diseases, does not represent the future treatment landscape, but the reality of today's treatment solutions. In turn, to provide the impactful value to our healthcare providers, patients, and clients in this new world, our scientific, strategic, and creative abilities will need to be even sharper and more insightful than ever before. By simplifying complexity into meaningful ideas that will inspire a generation, we can create a new level of optimism for previously unattainable patient outcomes.

Patient Journey

MICHELLE KEEFE
Global Group President and Chief Development Officer,
Publicis Health
PharmaVOICE Red Jacket honoree — 2016

There's already been plenty of talk about the importance and value of patient-centered healthcare, but I think we've finally reached a tipping point where the balance of power has shifted from institutions to individuals. Empowered patient-consumers are demanding more and providers in the total healthcare ecosystem will need to give patients greater, more active roles in their own care. As the industry shifts from addressing individual health on a case-by-case basis to managing population health to reduce health inequities across entire groups, the industry will continue to evolve from managing episodes of care to managing the entire patient journey across the full spectrum of care. Within the context of patient journeys, patient-consumers, physicians, and other caregivers each play critical roles to ensure improved outcomes rather than simply appropriate treatments are administered.

In the United States, the episodic, fee-for-service payment and care delivery model has already started to shift toward a population health and value reimbursement model. As a result, healthcare leaders are increasingly more focused on patient engagement to drive down costs and improve patient outcomes.

The once-fabled future state of when patient-consumers and providers are equal partners in planning, developing and monitoring care to make sure all needs are met is now.

CAROLYN MORGAN
President,
precisioneffect
PharmaVOICE 100 honoree — 2016

"Patient first" has been the buzz for quite some time. And while it's been more an ongoing commitment than a trend, I expect an uptick in focus from brand teams on user experience, particularly with regard to adherence and compliance. This is good news for patients and caregivers. Run-of-the-mill hub services, generic email campaigns, and brochures — these will no longer constitute a great patient experience.

We'll dig deeper into the patient journey and patients' unique behaviors to understand how experiences can be improved through customized and valuable touch points and services. Then with segmentation and technology, we can dramatically improve not only those critical first 30 days but also patients' ongoing relationship with the brand.

To be successful, content and experiences should match patients' varied needs. Everything ranging from insurance issues, therapy administration, patient support groups, support for HCPs, patient community groups, and ongoing disease state information should be available in all of the ways patients and caregivers like to consume them: phone, online, voice assist, AI, and at their physician's office.

A few pharma brands are doing this exceptionally well today. In the coming year, many others will race to catch up. And patients will be the real winners.

Personalized Medicine

DANIELLE BEDARD
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Managed Markets, part of INC Research/inVentiv Health
PharmaVOICE 100 honoree — 2017

Over the past 20 years, we've witnessed the transition of HIV from a death sentence to a chronic disease. In oncology, many types of cancer have become chronic conditions as targeted therapy, immunotherapy, antibody-drug conjugates, and CAR-T transform decades of research into new hope. We've even seen cures for hepatitis C and the reversal of vision loss due to diabetic retinopathy.

As the pharmaceutical industry has continued to develop life-prolonging and disease-defeating therapies, expectations have grown to match these evolving treatments. While at one time the North Star may have been delay of progression, incremental gains in survival, or successful management of symptoms, many of those goals have been reached — or may seem no longer to aim high enough.

The potential of a "cure" or "cure-like" therapies has changed the way providers approach treatment and patients think about their illnesses. Payers have begun modifying their approach to managing certain diseases, as short-term treatment yields to long-term care.

Even the concept of "improvement" is evolving. We've seen oncology recommendations that define clinically meaningful outcomes as improvement in survival of up to 40% over the existing standard of care. In multiple sclerosis, researchers and advocates work to make "no evidence of disease activity" (NEDA) a therapeutic goal. In rheumatoid arthritis, treatment goals look beyond signs and symptoms to the inhibition of joint damage.

Ongoing debate surrounds when to treat, how to treat, and even when to wait and "warehouse" patients who can wait for improved therapeutic options to be requested by providers, recommended by guidelines, and covered by payers. With the evolution of targeted therapy and personalized medicine, as well as orphan drugs for disease states with significant unmet need, the bar — and the stakes — will continue to be raised.

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One prevailing trend impacting the industry has been the amazing advancement in genomics personalized medicine. The idea that our treatment can be tailored specifically to individuals to determine, beyond the predetermined standard of care, how well a given treatment or therapy might work for each individual, is amazing. We have already seen great strides in the impact this precision approach has made across various forms of cancer. Through these advances we are gathering incredible amounts of health information and are only scratching the surface as to how to maximize this information for the benefit of patients. The age of "one-size-fits-all" care is over and perhaps these great advances will lead us as patients to be more educated, invested, and accountable for our own care than ever before. Alongside the amazing opportunities presented by this new targeted genomic data, we also face new ethical and practical dilemmas regarding issues of access and confidentiality. How we continue to navigate these challenges and further expand the impact of personalized medicine across more indications will make the practice more commonplace and, ultimately, the new standard of care.