Trend Tracking

As we gear up for 2018, we have identified 10 trends that are anticipated to have a meaningful impact next year. PharmaVOICE decided to rev up the "way-back machine" to revisit some of the trends from 2016 and 2015. Connect to our digital edition, to see how we did.

In this special — 2018 Year in Preview — issue, PharmaVOICE's thought leaders are tackling 10 trends that are expected to incite change in the year ahead. We will be looking at a variety of disparate topics that range from molecule to market in keeping with our publishing focus and philosophy:

2018 Year in Preview Trends

- Agile Marketing
- Alternative Healthcare Delivery
- Artificial Intelligence
- Bioethics
- Brand Engagement
- Pipeline Disrupters
- Rare Diseases
- Real-World Outcomes
- Treatment to Wellness
- Virtual Health Technology

The companies that comprise the life-sciences industry continue to face a world full of uncertainty, something they have been accustomed to over the past couple of decades. Pharma, biotech, and biopharma companies and their supporting partners face issues surrounding cost and pricing, innovation from molecule to market, customer — patient and physician — engagement, and regulatory hurdles. Layered on top are technologies that are evolving faster than companies and regulators can keep pace with, but they will need to because their main constituencies — patients and caregivers — are adopting new tools, solutions, and processes that make their life easier and healthier.

In addition, according to Deloitte, new and evolving technology advancements — more sophisticated electronic medical records (EMRs), wearable healthcare devices, next-generation sequencing, breakthroughs in genomics, immunotherapy, and gene therapy, and use of real-world evidence (RWE) and data analytics — are priming the life-sciences sector for disruption.

And with innovation comes growth. A quick look at Deloitte's global healthcare numbers tells an interesting story.

- Global healthcare expenditures are projected to reach $8.7 trillion by 2020, from $7 trillion in 2015, driven by improving treatments in therapeutic areas coupled with rising labor costs and increased life expectancy.
- Healthcare spending as a percentage of gross domestic product (GDP) should also rise slightly, from an estimated 10.4% in 2015 to 10.5% in 2020. Government healthcare expenditures as a percentage of GDP are projected to rise more quickly in low-income countries than other income groups.
- Chronic diseases are on the rise, assisted by rapid urbanization, sedentary lifestyles, changing diets, and rising obesity levels. By 2020, 50% of global healthcare expenditures — about $4 trillion — will be spent on three leading causes of death: cardiovascular diseases, cancer, and respiratory diseases.

Although pharma companies continue to deal with the repercussions of patent expiries and payers' cost control efforts, the growing acceptance of sometimes high-priced innovative orphan drugs and ongoing industry consolidation are expected to drive sales growth for the next several years. Deloitte analysts report that in 2015 there was a drop in total global pharma sales, in nominal U.S.-dollar terms, due to exchange-rate effect and the impact of cost control efforts in several markets, but sales are expected to improve from now until 2020, growing at an average of 4.4% annually to total a projected $1.2 trillion.

Evaluate, predicts a slightly higher forecast for worldwide prescription drug sales at a robust 6.5% (CAGR) through 2022 to reach $1.06 trillion, with 32% of the 2022 increase in sales to come from orphan drugs — $95 billion.

These projections were made before the election of Donald J. Trump, and amid the uncertainty surrounding the Affordable Care Act and funding of the FDA and the NIH, time will only tell what the fall out will be as Congress continues to struggle with finding a replacement healthcare policy and recognizing the importance of funding science. Like everyone else, PharmaVOICE will continue to wait and see what happens and provide updates as they occur.

Speaking of updates, this year, PharmaVOICE also decided to take a look back on the trends we identified in 2015 (Year in Preview 2016) and 2016 (Year in Preview 2017) to see if we hit the mark or not. We tapped our esteemed community of thought leaders to provide us with a frank evaluation on a number of these trends to see how their predictions are holding up against today's current market factors and if the industry is making progress or if it is stalled on the tracks. I encourage you to log on to our digital issue to read how these trends are tracking.

We stand by our tagline: Read. Think. Participate. We hope you enjoy this special Year in Preview issue.

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2018 What the Future Holds…

MARC BENJAMIN
CEO, Convergence Point Media

2018 will be the year that cross-audience synchronization takes hold as a force that defines effective pharma marketing. The endpoint of marketing programs will lean heavily on the occurrence and content of individual patient/physician communications. For the first time, the conditions now exist to facilitate the marriage of data-driven audience targeting techniques and human audience perspectives that define the behaviors and beliefs that shape each patient's medical treatment regimen. On the data side, the intersection of programmatic targeting, de-identified consumer health data, and precision geo-targeting raise marketers' confidence that they can pair messaging to align individual patient attitudes with unique target physician segment messaging priorities. As to the content itself, improvements in nearly real-time crowd-sourced survey and stimulus/response tools allow brands to cultivate the most relevant and compelling messages to spark desired action.

DAVID CONNELLY
CEO, Cmed

2018 will see the industry accelerate joining the dots when it comes to running digital clinical trials. Our industry has historically been slow to embrace new technology, often running dated systems that have limited interoperability. This results in clinical trial data being fragmented and aged by the time it can be reviewed.

Using modern technologies that have transformed our everyday lives, such as smart devices, apps, and sharing of information and media, clinical trials can be streamlined and costs reduced. All clinical trial data, whether from patients in the clinic or in their homes, including laboratory data, digital biomarkers and sensor data, ECG, medical images etc. can be captured live — or near live — held in one repository from the very start, and visualized through advanced analytics.

Increasingly, source data review will be reduced, simplified, or eliminated, data quality improved, and clinical data science will replace traditional data monitoring roles. Insights and analytics applied to data will become live and more sophisticated, with greater use of predictive algorithms and even artificial intelligence.

This immediacy of information and the ability to act will improve protocol compliance, patient safety, agility of trial design, and speed of decisions.

As more genetically modified cell treatments are developed, such as Kymriah from Novartis, the value of many Phase III trials will be increasingly questioned as continued "testing" under "rolling" licenses in real-world environments becomes possible. The convergence between the clinical trial and healthcare setting could even provide more evidence to support outcomes-based pricing.

JOACHIM FRUEBIS
Senior VP, Development, Bioverativ

There are several trends driving the increased interest in rare disease drug development. In general, the industry has seen a greater scrutiny of new therapies that demonstrate only a modest improvement over existing treatments, resulting in a more challenging environment for regulatory approval or meaningful reimbursement by payers. Additionally, indication areas that have historically played major roles in drug development, such as anti-thrombotic cardiovascular drugs, have seen market saturation with newer and more effective therapies. This increasing number of therapeutic options is making it more difficult to demonstrate superiority over existing products, often resulting in the need for large and costly clinical trials that are prohibitive to even the largest pharmaceutical companies due to feasibility and risk.

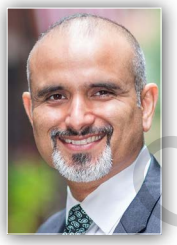
Considering this, developing therapies in the rare disease space presents a more attractive option. Unmet clinical need is generally high, making it easier to develop differentiated products, although we are starting to see significant me-too type development activities. Development typically requires smaller patient numbers, though it may still require large global trials to identify rare disease patients. Often trials can be faster, receiving favorable regulatory review options such as breakthrough designation and orphan drug status. These factors make development efforts, even by smaller companies, feasible. Novel technology platforms, including cell and gene therapy, are gaining in acceptance and are particularly applicable to rare, inherited, and monogenic diseases. Attractive reimbursement for drugs in areas of unmet need is not uncommon, but we are starting to see increasing pressure driven by competition and payer resistance. These factors, combined with the desire to develop therapies that can help transform patients' lives, are driving more companies into the rare disease space.

JEFF LEE
President, mProve Health

With the trend toward modernizing clinical trials and exploring virtual trial study designs, we are seeing new technologies such as engagement apps, eConsent, BYOD, ePRO, alumni networks, wearables, sensors, etc., being deployed. While patient-facing technology can be a valuable asset for engage-

ment and data collection, it can also place a burden on patients to learn new software and devices, access multiple systems, and be compliant with unfamiliar technology. In 2018, I expect our industry will focus on how to make it easier for patients to use clinical trial technologies. One clear path to doing that is merging and integrating technologies to reduce the number of touchpoints the patient has.

Today, many of the technologies I listed above are provided by "point solution" vendors, which often means that a single clinical trial will need to use several completely disparate systems. To address the challenges this creates, life science companies are looking to vendors to work closely together to streamline the patient experience. Our recent partnership with Greenphire, which integrated ClinCard payment information into mProve's patient engagement app, is a good example of the type of cross-vendor collaboration needed. I hope that these types of partnerships are more widely embraced by solution providers. As an industry, we must act to ensure that we do not place an untenable expectation on patients. If we put patients first, we can find ways to merge our technologies and make joining a clinical trial as easy as buying products from the Apple Store.



ANDY MEHROTRA
CEO and Founder, EightSpokes

I find modern truth in ancient Chinese wisdom, that the journey of a thousand miles depends upon every small step along the way. Nowhere does this ring truer than in the life sciences, where the success of complicated, multistep plans for drug development and commercialization ultimately depends upon the quality of work being delivered by each team member for every assigned deliverable. However, companies are limited in their ability to assess execution along the way. Often, they can only gauge the quality of work retroactively, when it's too late — this is unacceptable and will start to change in 2018.

Modern technology will finally enable real-time feedback from peers and managers throughout the lifecycle of a project so that every task achieves its intended outcome. Task members will receive relevant, timely assessment on their work so they can course-correct while their projects are still ongoing to improve overall quality, prevent costly delays, and increase productivity. Further, receiving on-the-job feedback and recognition will raise the team's engagement with their work — something that, according to Gallup, has been lacking in organizations globally for decades and is particularly important to millennials, who now comprise the largest share of the American workforce. The increasing power of cloud computing is eliminating delays and making continuous improvement through ongoing feedback a reality moving forward.

PATRICK RICHARD
Managing Director, Data Science, INC Research/inVentiv Health

One of the key trends that I've seen start to become a reality in the last year is the integration of data platforms to make more precise decisions. In our work we've seen less of a toe dip into using data regularly, and more of a proactive stance to make it a natural component of decision making. Examples of this can be seen broadly whether it is investment in a fully comprehensive data management platform, investment in internal or agency expertise, data automation, or all of the above. The refreshing part of this trend coming to life is that it doesn't just involve data analysts either. Many of these platforms visualize data on the front end in a way that's intuitive, actionable and relevant for the most part across teams. This allows strategists, marketers, creative professionals and of course data savvy team members to see the reality of what's actually happening in order to make a connection with their audience. Finding the right patterns out of the data you have available are where many winning insights are going to be formed. This all comes back to the right technology stack, and a diverse group of minds to find those key answers that make a difference.

ANDREI SORAN
CEO and Chairman, Novaseek Research
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Data access will level the playing field, enabling life-science researchers to identify a much broader range of patients in local and community hospital settings than ever before. Historically, the challenging and painfully slow process of enrolling patients for clinical trials has taken place through physician referrals from large, urban care centers.

Today, hospitals large and small are able to present patient-consented EMR data, cutting-edge communications tools, and annotated prospective specimens to researchers, thereby allowing nonurban patients and their local physicians the ability to participate in the trial process.

Second, in addition to providing clinical researchers with access to larger populations of patients from a variety of geographical settings, hospitals and laboratories can use this valuable data and corresponding specimens as a means toward additional revenue streams.

Technology and data represent the great equalizer for life-science companies and hospital/large practices to advance medicine for patients while experiencing mutual benefit.

2017 Year in Preview Trends Revisited

2017 Year in Preview Trends

- Cancer Moonshot
- Combination Therapies
- Gene Editing
- Health Bots
- The Industrial Internet
- Precision Medicine
- Smart Technology
- Talent War
- Triple Aim
- Virtual Reality

* As published in the 2016 November/December issue.

Cancer Moonshot

Oncology Pipeline is Promising

The late-stage oncology pipeline is robust with **631 unique molecules** in development. That marks a **7.7% increase** from the 586 oncology molecules in advanced-stage clinical research just a year ago. During the past five years, clinical development has become more efficient with shortened research-cycle times — particularly within Phase III trials for new cancer medicines, according to new research from the QuintilesIMS Institute.

The study found global spending of oncology therapeutics and supportive care drugs increased to **$113 billion in 2016** from $107 billion in 2015. The total global cost of cancer medicines rose at a constant annual growth rate (CAGR) of 8.7% during the past five years. That marks a noticeable increase compared with the 4.9% growth recorded between 2006 and 2011.

"The launch of multiple novel agents, coupled with increasing awareness and focus on cancer prevention, and emphasis on early diagnosis, have contributed to improved outcomes and a reduction in mortality rates for many of the major cancers over the past decade," says Murray Aitken, senior VP and executive director of the QuintilesIMS Institute. Mr. Aitken is also a 2005 PharmaVOICE 100 honoree.

JAI BALKISSOON, M.D.
VP, Immuno-Oncology Global Product Development, PPD

Compared with a year ago, funding for the Cancer Moonshot is less clear due to potential government budget cuts. However, indications are that nonprofit and corporate entities may step in to fill the possible void that could result, reflecting the desire on many fronts to move the initiative forward. Along with that effort, there's been strong interest in developing better immunotherapies, and there is related excitement about developing combination immunotherapies both in solid tumors and hematologic malignancies. Much of that enthusiasm is driven by the unprecedented number of breakthrough designations, priority reviews, and regulatory approvals that are occurring with the current generation of oncology immunotherapies.

GREG DOMBAL
Chief Operating Officer, Halloran Consulting Group
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Earlier this year, we described an unprecedented level of collaboration that would be foundational and simultaneously enable activity for former VP Joe Biden's cancer moonshot to become a reality. Since then, there has been collaboration between researchers, physicians, pharma companies, patients, diagnostic companies, hospitals, big data providers, government, and payers in virtually every direction. This matrix of collaboration might help us disentangle the massive and complex web of DNA defects, environmental factors, and genetic mutations that always seem to outsmart each and every approach to treating cancer. We are now starting to see the fruits of those collaborations — from the first CAR-T approval to active discussion on using real-world evidence to inform drug development. Data are beginning to inform our actions, but big data, even when combined with artificial intelligence (AI) is not the only answer. AI is not going to uncover new breakthrough combinations of treatments because AI has to learn — learn the pathways that trigger cancer, the survival mechanisms of each mutated cell, and better understand the complex realities of human medical care.

There is a significant way to go and untold scientific hurdles to overcome, yet progress is being made and hope for the future springs.

CURT STAAB
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The White House's Cancer Moon Shot initiative aims to make more therapies available to more patients, while also improving the ability to prevent cancer and detect it at an early stage. Many biotech companies have focused on developing and commercializing cancer immunotherapies that use the body's immune system to fight cancer cells.

While the clinical and regulatory hurdles for cancer immunotherapy approvals can be daunting, last year we reviewed the challenge biotech companies have in commercializing these products. As one executive interviewed explained, "Finding the right people is one of the biggest challenges we've had, and it is one of the goals we have most consistently missed."

This demand for commercial experience to ensure that patients get on the correct immunotherapy is demonstrated by the fact that some positions focused on commercializing cancer products earn a 31% premium over those focused on primary care products, an increase of seven percentage points from last year, according to TGaS data. Not only is compensation higher for oncology commercialization experience, but 63% of companies

also provide greater flexibility by allowing telecommuting for director-level positions, according to a recent TGaS survey.

While cancer immunotherapy will undoubtedly save lives, without the ability to quickly commercialize these products, patients will not receive them in a timely manner.

KILIAN WEISS
General Manager of KOL Solutions
Veeva Systems
kilian.weiss@veeva.com
2016 PharmaVOICE 100 honoree

Product launches are on every pharmaceutical executive's mind, especially oncology. The relationship between key opinion leaders (KOLs) in oncology and drug manufacturers is increasingly important to commercialization but no reliable technology solution exists today.

Treatment complexity in oncology is exponentially growing. It impacts everything from clinical trials to commercial models. To navigate this complexity, we believe a more strategic dialogue between life-sciences executives and the scientific community is needed. It enables the industry to make more informed strategic decisions — for example, in designing clinical trials. It helps the scientific community reach local physicians and translate its work into clinical practice around the world. Today, it is hard for both parties to communicate with each other. It often takes weeks, sometimes months, to identify experts because most of the existing data sources are highly fragmented. And, third parties restrict access or the dialogue is limited to small groups of friends. In 2018, the industry is going to need to figure out how to better connect the dots globally. Data and supporting technology will become key drivers to connect science and life sciences to drive patient outcomes.

Combination Therapies

CRAIG BAKER
Executive VP
Noble

Combination products and patient empowerment are still very much as relevant today as they were last year. Anaphylaxis and food allergies are increasing in prevalence around the world and are majorly responsible for the growth of the autoinjector market, which is projected to reach $2.9 billion by 2022. While autoinjectors have been redesigned for easier use, the onboarding period is still the most significant phase for healthcare industry participants to help patients build a sense of empowerment in their treatment, as well as to ensure long-term patient adherence and outcomes. Studies show that during the onboarding phase, 45% of patients skip or avoid injections due to needle anxiety or fear, which can lead to avoidance behaviors and ultimately the discontinuation of treatment. The development of novel needle simulation technologies that fully mimic the deformation, puncture, and insertion force characteristics of syringe needles have allowed patients to safely understand the force and technique required to insert a needle into subcutaneous tissue. This helps reduce anxiety for patients and empowers them to overcome the emotional barriers of self-injecting.

PAUL BALAGOT
Chief Experience Officer, precisioneffect

In looking at the latest trends in combination products, the future remains and bright. According to BCC Research, sales of drug-device combination products reached $21.4 billion in 2013 and $22 billion in 2014. This market is expected to grow to $31 billion in 2019, with a compound annual growth rate (CAGR) of 7.1% from 2014 to 2019.

There are a couple of factors that provide ongoing and future support for this trend. The first is precision medicine and the growing promise and demand for more individualized care positions the use of tech-powered devices squarely in the middle of delivering on that promise. Second, tech giants have come to play. Companies like Alphabet, Amazon, and Apple are investing heavily in healthcare as they find the industry ripe for disruption. These giants are collaborating with pharma and biotech in various ways to transform and improve healthcare from drug development all the way through delivery. And although their exact influence on combination products is not extensive today, I believe it's only a matter of time before their prowess in miniaturizing technology gets further integrated into this product category and possibly expands it. For example, could we see a day where our definition of drug/device combination products broadens to include diagnostic properties?

The growing demand for precision medicine coupled with ongoing advancements in technology uniquely positions combination products as drivers for pushing the healthcare industry forward.

As the market continues to embrace these trends, I expect to see further innovation and expansion of the category.

JAI BALKISSOON, M.D.
VP, Immuno-oncology Global Product Development , PPD

With the increasing number of checkpoint inhibitor approvals in 2017 there is more enthusiasm from sponsors to combine novel agents with these checkpoint inhibitor monotherapies. Multiple agents that inhibit immune suppression in the tumor microenvironment, increase tumor neoantigens, or transform a "cold" tumor into an "inflamed" tumor are being combined with checkpoint inhibitors. The goal is to have more patients respond to these combination therapies and that these responses be durable. The traditional development platforms for these combination immunotherapies are also changing. There is now more emphasis on large early phase basket trials that are designed to identify tumor types most likely to respond to these immunotherapies. We are also seeing approvals of immunotherapies based on molecular signatures that are agnostic to tumor type.

GREG DOMBAL
Chief Operating Officer
Halloran Consulting Group, @GDombal; @HalloranConsult

2017 has been a significant year for the development of the regulatory framework around combination products in the United States and Europe. In February of this past year, the European Medicines Agency (EMA) released a concept paper on its envisioned future state framework for efficient regulation of combination products.

While this is just a start for EMA, it is significant in that EMA dedicated human capital has been very present at industry gatherings. It's critical for EMA to discuss its position and gather industry views, while preparing for a relocation of its Canary Wharf HQ as a result of Brexit.

In the United States, the FDA formalized a guidance regarding the classification process for combination products. This guidance substantially increases the profile of the Office of Combination Products and helps shed light on a process that has evolved significantly over the past few years. Certainly, a company needs to be clear regarding what criteria will be used to determine whether a product will be approved via drug (NDA), biologic (BLA), or device (510k or PMA) paths. This guidance is timely as new combination products have been approved in the areas of diabetes, infectious disease, immunology, urology, rheumatology, and oncology. These approvals include combinations of new products as well as new entities combined with previously approved products. In our practice, we are seeing a rapid rise in the number of clients that are seeking advice and strategic support for combination product development.

ELIZABETH MADICHIE
Global Head of Regulatory Affairs, PPD

Combination product guidance and legislative pathways have continued to evolve over the past year. For example, the 21st Century Cures Act (2016), adds new combination product regulations to the Federal Food, Drug and Cosmetics Act (FDCA). Before the Cures Act, sponsors relied on nonbinding guidance documents for recommendations on how to proceed with combination product research and development initiatives or would obtain agency feedback as to a product classification. The Cures Act includes many regulatory changes that are intended to improve and clarify how the FDA is to regulate combination products. These changes are significant in that they are designed to help sponsors and the FDA agree on the most efficient pathway toward market clearance or approval of innovative combination products.

In addition, the EU Commission has finalized the Medical Device Regulations (MDR) and In Vitro Diagnostic Device Regulations (IVDR). While neither the MDR nor the IVDR specifically address combination products, the new clinical data requirements may have a significant effect on combination products with a device lead. However, this may pose challenges to both the sponsor and regulatory agency, as the regulations are new and untested. The numbers and types of combination products continue to grow. The new regulations in the United States and European Union make effective regulatory capacity management even more critical to maintain agency review timeline compliance and facilitate the creation of proactive innovative regulatory pathways.

Gene Editing

LEE FRASER, PH.D.
Senior VP SciMed, Digitas Health

When we last talked about gene editing — CRISPR — I mentioned "the simplicity and versatility provide the promise of practical clinical genetic manipulation in the near future."

I think it is clear that we are continuing to see the potential of CRISPR moving forward in the lab, and more interestingly, in the clinic. At present, there are approximately 20 human clinical trials ongoing or about to start including the first attempts to use CRISPR to edit cells while they are inside the body. While the application of the technology on a molecular level is theoretically unlimited, the ability to use it in vivo is a key hurdle. In parallel to the growth of clinical trials, technology is also evolving to help better deliver CRISPR in vivo (e.g., nanoparticle encapsulation); this is the real key to pushing the clinical utility forward.

Health Bots

ERIK JONES
VP, User Experience and Data Science, Inspire

A great deal of progress has been made in the last year in the area of bots in the medical community. However, almost all of that progress has been "under the covers." Machine learning and natural language processing have made great strides, but this has not yet translated into mainstream adoption of bots as a technology, by pharmaceutical companies, health insurers, direct care organizations, or patients themselves.

There is as of yet no mainstream standard for exchange of health information between competing platforms, although I have hopes for FHIR (Fast Healthcare Interoperability Resources), which grew out of HL7. Given the narrow scope of medical chatbots, having this open standard is critical. The industry cannot allow itself to be trifurcated like the home sector is, with Google, Amazon, and Apple all competing with products that do not work together.

Other than the core technology itself, this is still the biggest obstacle toward widespread adoption of bots. Privacy and trust are still paramount when dealing with health data. But if a person's health information exists only on one platform, and cannot easily be accessed by other apps, this fledgling technology will fail to get off the ground

RITESH PATEL
Chief Digital Officer, WPP Health & Wellness

In 2016, we focused on chat bots and their potential for healthcare and pharma in particular. We envisioned a world of self-service using these semi-intelligent bots to take off in the sales, marketing, and patient-assistance world. Again, I fear we are about two to three years behind in this area from the other industries adopting them in droves. The only healthcare bots that have appeared in the market are consumer-facing ones in the United Kingdom and China with ada.com, your.md, and Sensely in the United Kingdom, and Baidu launching the Melody bot in China.

The opportunity to use chat bots for un-

branded campaigns, remote rep services, medical education on demand, patient assistance and disease education for "beyond the pill" services is immense. Now would be a good time for pharma to adopt them in the same way the rest of the world already has. So a mixed review of trends and predictions. Time will tell if my view of the future becomes reality within the coming year or if I'm jumping ahead a couple of years.

Industrial Internet

KENNETH FISHER
VP, Director of Technology GSW, part of INC Research/ inVentiv Health

The future of the Internet of Things (IOT) in medicine and health is here. The connected medical device market is primed to explode. In a report prepared by Allied Market Research, analysts valued the world of IoT at $60.4 billion in 2014, and projected it would swell to $136.8 billion by 2021.

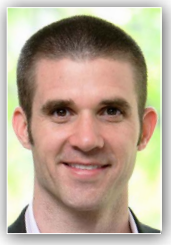
No matter the number, we know it is going to be big and lucrative. The competition is already fierce in both the medical device and consumer markets, from heart monitors that provide critical data about heart rhythms, to devices aimed at the health and lifestyle market, such as advanced fitness trackers that measure a host of biometric data to give you a snapshot of your physical state at any given time or time period.

Ingestible "smart pills" contain sensors that gather data for diagnostic purposes are steadily gaining in use. For example, these sensors have been used to analyze acid level, pressure, and temperature within the stomachs of patients with conditions such as gastroparesis.

This opportunity is attracting large technology companies, including Alphabet (Google), Apple, and IBM, with Apple recently applying for a patent for a wearable medical device that can be worn in many different ways.

Perhaps the most interesting are upstart companies that are innovating to address specific pain points, such as a pill bottle that helps to promote medication adherence.

This market, that did not exist just a few years ago, is at a moment when the potential reward is enormous, spurring innovation, and quite possible a host of applications that will benefit all of us.



BRIAN LONGO
General Manager and Senior VP of EDC Solutions, Veeva Systems
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2013 PharmaVOICE 100 honoree

The industrial Internet prediction I made last year appears to be a boon. It has begun to erode the siloes of data from patients, clinicians, CROs, and sponsors. The barriers separating these valuable data sets are crumbling, although not yet to scale. Life-sciences companies recognize that there is no room for delays or inefficiencies in drug development and are adopting next-generation technologies to close the information gaps between systems and enable real-time access to reliable clinical data.

New research by Tufts Center shows that most companies (77%) still have issues loading data into their primary EDC system while 66% cite system problems or integration issues as the top challenges that prevent them from loading data. But new, interoperable solutions have arrived for a unified clinical technology environment that will connect all of the data "dots" and enable early intervention, reduce redundancy and inefficiency, and speed time to market.

PATRICK RICHARD
Managing Director, Data Science INC Research/inVentiv Health

The biggest insight out of the Industrial Internet discussion last year is that it continues to be a living-breathing, large piece of the puzzle that puts the human being at the center of healthcare. It's not something that's easily assessed for progress because the upside and constant change in technology will always be present.

Precision Medicine

LEE FRASER, PH.D.
Senior VP, SciMed Digitas Health

When we last talked about precision medicine I mentioned that better identifying the underlying nature of disease would lead to better medicine. Keytruda recently provided a good example of how precision medicine is changing the way cancer drugs are studied, approved, and used in the new era of precision medicine.

In May of this year we saw the approval of Keytruda for the first cancer indication agnostic of anatomy. Keytruda was approved for both adult and pediatric patients who have unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors. For the first time ever we have seen a drug approved based on a genetic signature independent of anatomy. The single approval was based on data from 149 patients with 15 different tumor types. While many cancer drugs are often used across multiple tumor types, this is the first time that a genetic test is the basis for approval to guide the use and the first time it was done in a single study.

ROBERT GROEBEL
VP Global Medical Strategy, Veeva Systems
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Last year, I asserted that patients would ultimately benefit from the combination of data-driven specialized care and precise treatments — and it's happening. This is becoming the standard, especially in oncology, where digital technologies have transformed care. Genomic testing has enabled personalized, patient-specific oncology treatments based on DNA test results. In certain types of cancer, tumors can grow rapidly or become resistant to therapy. With the significant advances made in immunotherapy, liquid biopsies are now more accessible to oncologists, delivering data on the specific molecular changes to a tumor in real time. Precision medicine will continue to drive exciting advances through new innovations focused on patient outcomes.

Commercial organizations must remain focused competitively, as requirements to demonstrate value and improve outcomes will only continue to increase. As we progress into 2018, the connected healthcare ecosystem must consider investment strategies that align both technical and human capabilities to remain relevant as the patient-care model continues to evolve. And, as noted last year, organizations will need to adopt modern enterprise systems that provide greater visibility for medical affairs teams that have grown both in quantity and importance to delivering on the promise of personalized medicines.

KERI HETTEL
Senior VP, Strategy & Analytics, Razorfish Health

The escalation in the use of precision medicine certainly met my expectation in 2017. The healthcare space has continued to become more and more crowded, with a tremendous number of drugs available in many classes, for example, rheumatoid arthritis, diabetes, etc. At the same time, the marketing space continues to overwhelm the consumer with ads and branded content. The growth and accessibility of data grew a lot in 2017, with areas like artificial intelligence (AI) spotlighting the enormous opportunity that data can play in everyday lives.

Precision medicine presents as the only way to address the convergence of both the volume of treatments, medicines, and solutions in tandem with marketing. Further, today's patients expect personalized care, and the extension of that care to their life away from treatment. AI and other types of data and technology advancements continue to enable personalized communications around treatments, which are at the heart of precision medicine. This trend will only continue and accelerate in the year ahead.

CHITRA LELE, M.D.
Chief Scientific Officer, Sciformix
2014 PharmaVOICE 100 honoree

Advances in and increased use of pharmacogenomics and pharmacogenetics has led to a greater appreciation of the importance of genetics in explaining the variability in how individual patients respond to drugs both with benefits and risks. This progress and further developments in next-generation sequencing and information technology has helped advancements in precision medicine. For example, a large number — 41% — of new drug approvals in 2016 treat rare diseases and that trend is continuing in 2017.

Furthermore, the FDA has launched the Precision Medicine Initiative, which aims to understand how a person's genetics, environment, and lifestyle can help determine the best approach to prevent or treat disease. Two recent approvals illustrate the FDA's focus: Kalydeco for cystic fibrosis, with expanded approval for 33 cystic fibrosis mutations — up from 10 previously — and expanded approval for Keytruda for patients whose cancers have a specific genetic feature.

Thus, precision medicine is clearly turning out to be a boon, but before it can be unequivocally declared as such, the challenges of bench-to-bedside implementation and delivery have to be addressed. These are primarily related to healthcare regulations and government/regulatory priorities, and how they vary even between the developed nations. This impacts patient access. Another illustration of the heterogeneity is the pharmacogenetic information in drug labels of various regulatory agencies, which impacts implementation.

LINDSAY MCNAIR, M.D.
Chief Medical Officer, WIRB-Copernicus Group, @WCGClinical

For a few years, precision medicine has been a catchphrase touted as the future direction of medical innovation. Is that prediction holding true? The answer seems to be yes, so far. Dr. Janet Woodcock of the FDA reported recently that CDER approved 25 targeted therapies in the past three years, and has approved secondary indications based on specific genetic markers for several drugs already on the market. Advances in biomarker technology and the use of genetic testing to identify subsets of populations most likely to respond to new therapies continue to refine the design of clinical protocols, and we see a general trend that clinical trials are smaller and more focused on specific patient groups. Regulatory efforts, including the 21st Century Cures Act, support the development of targeted therapies. At the same time, public health experts point out that while therapies become targeted to small populations, we need to make sure these efforts remain integrated with population health goals so that we don't develop tremendously effective medications that work for only very small numbers of people. All of the parties involved in research — biopharma sponsors, researchers, ethicists, and patient advocates — will need to continue to work together to ensure these goals.

JUDITH NG-CASHIN, M.D.
Chief Scientific Officer INC Research/inVentiv Health

Precision medicine — identifying the right patient for the right intervention — should increase the probability of clinical efficacy and, therefore, lead to improved physician confidence in the therapy, increased likelihood of payer reimbursement, and improved patient access. While there are many indicators that reflect acceptance and progress in the field, the full promise of precision medicine approaches remains to be completely realized.

Our scientific understanding of the interface of disease biology and genomics, proteomics, and other sequencing capabilities has encouraged an increase in identification of molecular targets and associated therapy development programs across the industry, from academics to small biotech and large pharma companies. Recent regulatory approvals indicate an encouraging future for this approach. Over the last three years, the FDA (CDER) has approved more than 25 new therapies that target patients with specific genetic characteristics. In addition, this May the FDA announced approval for Keytruda (pembrolizumab) to treat cancers with a specific genetic characteristic — an unprecedented indication, as typically tissue of origin has been used to define cancer type.

However, targeted therapies require identification of the intended target. This is where further development is needed. Companion diagnostics and biomarkers that enable identification of the appropriate patients with the intended target and/or that measure the efficacy of the intervention must become more available and affordable. Many targets of drug development are genomic. A data infrastructure that makes these results easily searchable is critical to identifying the appropriate patients for a particular therapy.

Precision medicine should more accurately

identify patients who are most likely to respond to treatment. This is in line with the payer focus of value-based medicine, in that patients who are unlikely to respond to a given therapy will be screened out before a prescription is even written. That value represents a long-term cost savings. In the short term, however, payers could see expensive molecular diagnostics needed for screening as a challenging cost burden.

The good news is that these hurdles are being addressed with advancing biomarker science, decreasing cost of sequencing technologies, engagement of technology companies and government on data infrastructure, and a shifting focus to value-based care. As these fields progress, the probability that precision medicine will deliver more scalable, patient-centric, effective care over time should improve.

RICHARD TSAI
VP, Marketing, Inspire

We'll see the growth inflection point of the precision medicine industry within the next five years. We're moving toward a more patient-centered holistic approach — a paradigm that uses a multifactorial approach by leveraging a diverse set of data to tailor the prevention and treatment of disease, or care of individual patients.

Much of the current growth results from the convergence and adoption of newer technologies into the healthcare ecosystem. Examples include radiogenomics, that links genotypic to phenotypic imaging data, and deep learning/AI methods to train computers to grade cancer tissue slides. However, advancements hinge on the often-difficult challenge of integrating disparate data sources and types.

On the patient front, we see mixed sentiments regarding precision medicine. Some patients worry how their data might negatively impact their health insurance, and others are less concerned about that risk, and are more optimistic about what precision medicine can offer. On a recent survey of patients on Inspire, 60% of respondents said they were willing to share their genetic data with a researcher, but under 10% would share that information with an insurer or pharmaceutical company. This is a reminder that as we continue to push precision medicine forward, we must involve patients in all facets.

JOY YUCAITIS
Senior Director, Oncology Strategy
Novella Clinical

Precision medicine is definitely here to stay. Almost as soon as new drug targets are identified, new treatments enter the clinic. These new targets very often require a companion diagnostic, driving more innovation and commercial activity. Use of targeted therapies is rising quickly in terms of prescriptions, and even more quickly in terms of costs, accounting for 12.3% of prescriptions and as much as 41.6% of costs for antineoplastic agents in one study. One can argue that some of these costs are mitigated by a reduction in expenditures for noneffective treatments as well as a reduction in costs to manage adverse reactions. An analysis of the cost-effectiveness of anti-EGFR antibodies in chemo-resistant colorectal cancer failed to meet the threshold, consistent with the NICE 2012 opinion in the United Kingdom that these drugs do not provide sufficient benefit to justify the cost. While precision medicine is good news for cancer patients, we must prepare for the impact on healthcare costs and implications for reimbursement.

Smart Technology

DAVID MOORE
Executive Director
Ashfield Healthcare Communications, part of UDG Healthcare plc

Health tech clearly, across the board in a broader world, has continued to grow very rapidly, but on the work we do with healthcare clients, the role it has played has been a little slower. It is being used for patient support in collecting data on chronic conditions and in rehabilitation. For example, we are working on a program to improve adherence to cardiovascular rehabilitation, where the requisite exercise and dietary information can be simply recorded on a wrist device. Initial data indicates patient adherence is up significantly as a result.

However, the big question is, how do we transport these successes to support consumer wellness? The key will be determining how we can strengthen the relationship between the patient and the healthcare professional to improve adherence. Can the device provide data directly to the physician so that on a daily basis a cardiologist can pull up patient stats, and realize if the patient is in danger of an event. It becomes a little bit preventative, a little bit diagnostic, but ultimately, rather than visiting the hospital once a month, or taking a hospital bed for three days, physicians get a more personalized view of their patients' health, affording them the opportunity to make good medical decisions.

Talent Wars

LAURIE HALLORAN
CEO and President
Halloran Consulting Group, @LaurieAHalloran
2010 PharmaVOICE 100 honoree

Life-science discoveries continue without any apparent abatement. The discovery and early development world has evolved in proportion to the funding that is out there, and with no surprises, the life-sciences industry seems to be awash with opportunity. It gets more complex when laboratory work evolves into the intense human capital phases of later development.

There has been a trend throughout all industries to outsource non-core activities, but this is where the challenges lie in clinical development. As the volume of new products entering clinical development expands, there are ever-greater pressures on the outsourcing providers, particular CROs. The CRO market is suffering from what amounts to a collapse of the largest tier of vendors into a few major players at the top end. At the other end, there are hundreds, if not thousands, of specialty companies that are too small to compete on most programs. As the CRO market at the top has consolidated, this enormous competition is paralleled with a decrease in overall client satisfaction. This isn't a new phenomenon, but it gets worse each year.

The second challenge is the combination of workers in the Millennial generation, who have little patience to gain experiences, and the dramatically increased need for experienced workers. This combination is driving up salaries and intensifying competition for all levels of talent.

We're constantly recruiting for candidates with elusive, deep experience in technical skills combined with a consulting mindset.

TIM WOHLGEMUT
Senior VP,
TGaS Insights
Tim.wohlgemut@tgas.com; @tgasadvisors

The talent war trend continues. While big pharma may have taken a small pause in growth due to pricing and payer uncertainty, the constant pull to small biotechs has meant that the war for talent continues unabated. Those with experience in specialty, rare, infectious disease, and oncology are in particular demand. And with so many companies appearing in the new hotspots of Boston, San Diego, and San Francisco, the ability to attract talent in those locales has been hampered by high demand and limited supply.

Workforce Marketplace

New flexible workforce solutions, such as on-demand labor platforms, will be key to unlocking innovation and organizational changes.

73% of life-sciences executives agree that their organizations are under extreme pressure to extend innovation into their workforce and corporate structure.

Source: Accenture

Triple Aim

JENNIFER FILLMAN
VP/General Manager,
Specialty Services
Cardinal Health
Specialty Solutions

Introduced in 2007, the Triple Aim Initiative seeks to improve the effectiveness of healthcare, decrease costs and increase patient satisfaction. While much activity has occurred the past 10 years, it is difficult to conclude whether the Triple Aim is a boon or a bust. On the issue of cost, the introduction of the Medicare Access and CHIP Reauthorization Act (MACRA) has started to move healthcare providers toward value-based reimbursement, but most of today's incentives still reinforce the fee-for-service model. The growing prevalence of electronic medical records (EMR) has been a positive step toward improving effectiveness, but we still struggle with how to share information across the system and bring value from the data. Patient satisfaction is the area where we have made the most headway. Healthcare stakeholders including providers, pharmacists and drug manufacturers are focused on understanding how patients define value and refining their services to be more patient centric. At the same time, patient-reported outcomes are being routinely collected and analyzed to influence everything from treatment decisions to payer negotiations. While the cost and effectiveness goals may still be aspirational, the shift toward greater patient centricity is certainly a sign of improvement for the industry.

MICHAEL ZILLIGEN
President, Payer Marketing,
Ogilvy CommonHealth Worldwide, a WPP Health & Wellness company

Triple Aim was named after three core components to improve health system performance: improving the patient's care experience by implementing quality and satisfaction programs and metrics, addressing population health concerns through the development of population management tools, and reducing the per capita costs of all healthcare expenditures.

While the overall goal of the Triple Aim of healthcare is a lofty one, it is certainly achievable, albeit it is more complex and has taken longer than anticipated. And there are certainly examples of healthcare organizations such as CareOregon and Genesys Health System that have been truly successful exist, they are in the minority.

What has made this initiative both challenging — and potentially transformational — to date is the gap between individual patient treatment needs and those of the patient population and alignment of incentives.

While Triple Aim strives for lower per capita healthcare spending across a population, the individual treatment decisions made at the patient-physician level may not have cost or utilization as a primary consideration.

So progress within the constraints of the present healthcare system will continue to be incremental, as healthcare organizations continue to evolve and incentives become more aligned, but only time will tell.

Virtual Reality

DREW GRIFFIN
Senior Technical Architect,
Razorfish Health

The virtual reality/augmented reality (VR/AR) trend is very much on target, as evidenced by the sheer number of VR/AR stories that continue to appear in mainstream news outlets.

The increased rate of adoption across the health and wellness spectrum is due in large part to a proliferation of tools in 2017 that are allowing software developers and architects to embed VR and AR into mobile and desktop platforms.

Apple released ARKit, which allows developers to embed augmented reality components into iOS applications, and Google has released ARCode, which provides similar functions on Android devices. Google has also added support for WebVR into its Chrome Web browser, which means that virtual reality experiences are now possibilities on all major web browsers.

These new tools could start to manifest themselves with applications, such as displaying a heads-up model of a patient's mouth during oral surgery or allowing an occupational therapist to virtually walk through a patient's home to assess obstacles to activities of daily living. It is now easier than ever for innovators to build meaningful VR/AR experiences.

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Suman Dutta
Senior Quality Consultant
Boston Scientific

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2016 Year in Preview Trends Revisited

2016 Year in Preview Trends

- 21st Century Cure
- Analytics-Driven Approaches to Marketing
- The Brain
- Healthcare Disrupters: New Entrants
- Mobile Optimization
- New Health Economy
- Patient/Caregiver Empowerment
- Reputation Management
- Personalized Medicine
- Smart Medical Technology

* As published in the 2015 November/December issue.

Analytics-Driven Approaches

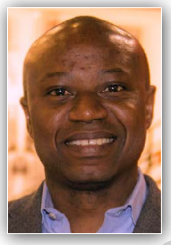
PATRICK HOMER
Principal Industry Consultant, Global Practice, Health and Life Sciences, SAS

Industry has advanced further and deeper into analytics-driven approaches to marketing by leveraging consulting vendors to provide that analytical insight. That's a positive sign and step in the right direction, but it's only the first phase.

The next phase of this analytical evolution is to leverage the industry's internal resources, the highly skilled management scientists. They need to be empowered with the next generation of available technologies to allow them to pursue a new dimension of analytics and insight that bring value to their organizations, rather than rely on the historical practices of outsourcing to develop analytically derived physician targeting and segmentation strategies and determining optimal marketing mix decisions. Bringing these capabilities back in house adds so much value.

Organizations are starting to see the value of internalizing their analytics and taking steps to develop an analytical platform to complement their other IT platforms that increase productivity and drive operational efficiency. Analytical platforms provide the foundational framework and a structured approach on how to develop these new capabilities.

The latest technologies that sit within this framework will also help to democratize the availability of advanced analytics across organizations by making it far easier to gain access to insight.



IYIOLA OBAYOMI
Senior Director, Marketing Analytics, Ogilvy CommonHealth Worldwide, a WPP Health & Wellness company

It has been two years since my recommendation that pharma companies must progress on three important fronts to adequately harness data-driven marketing's potential: upgrade analytics capabilities and infrastructure, invest in data and analytics talents to unlock the value, and embrace experimentation. I recognize that these are recommendations rather than predictions, but how have things fared today?

Much has happened along these three suggested areas: Larger and more varied datasets are being captured; partners and partnerships are providing and collaborating on data sharing; tools and platforms that promise advanced cognitive capabilities have matured; expanding analytics training and education have brought more talents online and the passage of time has also increased the experience and competence of practitioners; the appetite and curiosity for what data can do has noticeably grown among senior healthcare marketers; and technology and consumer firms have expanding cases that prove the value of in-market testing and adapted content.

Overall, pharma seems to have embraced and made progress along three areas, but at the expectedly varying pace by company. We have seen interesting use cases and clients that are more curious and demanding about harnessing these data-driven capabilities. Looking forward to 2018, I will make the same recommendations but with a few details. Pharma should: proceed with the capability enhancement in the form of ability to easily collaborate with the right partners — as the datasets will be too large or too expensive to own, and include AI and cognitive tools as part of staple tools; consolidate or foster closer partnerships between data-oriented centers of excellence — data, research, commercial analytics, and multichannel analytics; and embrace access to a wider array of content and message options to foster experiments tailored to increasingly micro-segmented or audiences of one.

Healthcare Disrupters

BRENDAN GALLAGHER
Executive VP, Connected Health Innovations, Digitas Health

The opportunity for tech giants and start-up companies to bring new commercial opportunities and R&D techniques has been a "boon" but it's certainly subjective depending on your perspective. From a tech giant standpoint, we stand on the precipice of Amazon entering the online pharmacy market and blowing it to bits. From a start-up standpoint, we saw an unprecedented amount of investment in potential digital health disruptors. If anything, the "bust" would be on most pharma companies, that failed to take advantage of key partnerships during this window.

Mobile Optimization

DAVID MOORE
Executive Director, Ashfield Healthcare Communications, part of UDG Healthcare plc

The trend to optimize the mobile platform in healthcare communications continues, so much so that in many of our programs we have adopted a "mobile-first" philosophy. This is a result of two factors: the real acceleration in our interaction with patients and the significant increase in the use of the mobile platform to access information, whether we are patients, consumers, or physicians. The ubiquity of mobile

devices has designated them the primary channel for healthcare outreach in many cases, replacing the laptop and television for the most part. And, the fact that the mobile platform ties in easily with social media, where patients and HCPs alike may enter a discussion and pick up new developments, only increases its value. Twitter, LinkedIn, as well as text messaging, and now, Instagram, are increasingly moving into the communication mix — all via the mobile platform. We have found the mobile platform particularly impactful when dealing with chronic diseases such as diabetes, cardiovascular conditions, or dermatology diseases, where the patient needs to provide regular information to the physician, maintain a patient diary, or gain access to a healthcare professional. Mobile is by far the best platform to achieve this.

No longer do we ask "what should we do in mobile?" That isn't even a discussion now; it's a given.

RITESH PATEL
Chief Digital Officer,
WPP Health & Wellness

So here we are hurtling toward 2018 – and all the uncertainty it has to offer. It's a good time to revisit some of the things that we suggested as trending in years gone by and see how we are doing.

In 2015, we focused on the immense growth of the smartphone and on mobile health in general. Almost all of the contributors to the trends article in 2015 were lamenting the lack of mobile expertise within pharma, and most importantly the impact it will have on advertising, marketing, and content. We were still living in the world of responsive design and an app for everything. Fast-forward two years and where are we?

While "mobile first" has become the mantra for a number of pharma companies that have finally woken up to the consumer experience on mobile, most are still living in the responsive design, "can we create an app?" world. Our customers, on the other hand, have completely migrated their health and wellness to the smartphone. Apps such as flo.health, which has 10 million women users, is grabbing market share from consumers, and Figure 1 is doing the same with HCPs. Pharma has been slow to change, and we are still not seeing the wide use of adoption of mobile first, mobile content strategies, and mobile engagement in the marketing vernacular.

However, all is not lost. The segment that is hurtling full speed toward the adoption of mobile and all it has to offer is in the clinical area of pharma, with folks like Medable and Science 37 being adopted and trialed. The managing of a clinical trial on mobile, with collection of data from sensors and mobile, is growing very fast. Some companies, like Janssen, are creating their own connected mobile clinical applications.

ALEX TSUI
Principal Industry Consultant, Health Care and Life Science Industry Solutions, SAS

In the last two years, the consumer enthusiasm for using mHealth apps and wearables to better manage their health and wellness continues to rise. At the same time, the need for pharmaceutical companies to provide real-world evidence (RWE) about the outcomes of their medicines is also increasing. As such, pharmaceutical companies have access to larger amounts of data than ever before and need to build an effective technology platform to systematically collect and analyze such info, generate relevant insights to help both the companies and patients. While still at an early stage, some marketers are starting to leverage mobile and RWE data analytics to help patients achieve better outcomes of the medicines.

We've also seen increased requirements for protecting personal information in the last couple of years with the May 25, 2018, deadline for GDPR as an example. With incidents like the Equifax data leak, patients and organizations storing patient data are increasingly concerned about the security of their data. Bringing transparency about how their data are handled and used is increasingly critical in the relationship building with patients and prescribers. Marketers must realize the sensitivities for some of the data they possess and seek out expertise and services, when needed, to ensure the proper governance and management of their data throughout the enterprise.

Smart Medical Technology

XAVIER FLINOIS
President,
Parexel Informatics

We have made significant steps in identifying how technologies, such as wearables, could address current challenges in clinical trials. While we have long believed that wearables have the potential to increase patient participation and engagement, create more opportunities for decentralized trial sites, and reduce the costs of trials, we are now at a point where this is being evaluated in clinical studies. Our recent collaboration with Sanofi aims to demonstrate the scientific and medical viability of wearables to remotely collect patient data, which could be transformative for the industry.

JENNIFER SIGAUD
Managing Director,
Atlantis Healthcare

Smart medical technology continues to impact how we capture data about people who have been diagnosed with a condition and are put on a treatment plan. There's been a proliferation of tools for pharma, healthcare plans, and other stakeholders to collect information about health behaviors, from wearables and apps to augmented reality. That said, there is opportunity for advancement in how the data are used.

It's critical that sponsors of patient support programs have a plan to evaluate data they collect, and apply those learnings to enhance future support.

Take a fitness tracker as an example. While it's great to know you've walked 5,200 steps today, the information doesn't really mean anything without context. What was your goal? How does it compare with yesterday, or last month? As your steps increase, what other health activity or metric is changing? Are you feeling less motivated to achieve your goals during the week vs. weekend? Why?

Likewise, it's no longer enough to passively collect data in patient-support programs. We must be proactive in using data to improve the patient support experience across multiple checkpoints. At the very least, we should leverage insights to create personalized messaging or to encourage HCPs to initiate a dialogue with patients about their treatment progress. PV