by Taren Grom

20 for 2020

1. What would it take for gene therapies to succeed after FDA approval?
2. What would be the impact of siteless trials on clinical development?
3. What would it take to develop drugs in real time for rare disease patients based on their genome affliction?
4. What impact will behavioral science have on marketing strategies/ initiatives in the future?
5. How can companies harness the power of social media community influencers as the new healthcare decision makers?
6. What role will the traditional pharma brand play in terms of value in the future?
7. What is the possibility that robots could replace physicians?
8. What if our health was managed by wearable clothing technologies?
9. How would patients benefit if home healthcare was powered by IoT?
10. What would need to change to have the industry move from treatment to prevention, diagnostics, and cure?

The Year Ahead...

We ask more than 130 experts, what needs to happen to address inefficiency and productivity to achieve aspirational goals for healthcare in the future.

For this year's special 2020 Year in Preview issue, we posed 20 provocative questions to our community of thought leaders, who represent all aspects of the life-sciences industry. We curated responses from more than 130 experts — the good news is that they don't all agree with each other. This was the point. We wanted to push the envelope to understand how the industry's influencers think about aspirational goals in terms of health, what needs to happen to address inefficiency and productivity, and what the future might hold for all of us as individuals who may be patients, patient caregivers, or patients-in-waiting.

We hope these questions, and our thought leaders' answers, incite you to think beyond the status quo and urge you to adopt an aspirational mindset to evolve the healthcare industry. PV

What if...

We provided our community of thought leaders with the opportunity to ask their own what if questions.

WHAT IF ... INNOVATION WERE BETTER FUNDED?

PAUL BALAGOT
Chief Experience Officer, precisioneffect

What if we introduced an innovation tax to fund basic medical research? Also, what if we focused on digital innovation to keep elders in their homes?

WHAT IF ... LIFE-SCIENCES COMPANIES AND PROVIDERS JOINED FORCES TO UNLOCK THE VALUE OF HEALTHCARE DATA?

JEAN DROUIN, M.D.
Co-Founder, CEO, Clarify Health Solutions

Healthcare providers and life-sciences organizations have a tremendous opportunity to work together to realize the full potential of accessible, interoperable, and actionable patient data. Imagine if we could improve the patient experience by adopting a more holistic approach, one in which all relevant data shape healthcare decisions in real time. Insights from healthcare information beyond traditional research settings, including EMRs, claims and billing, product and disease registries, personal devices, and social and behavioral determinants of health sources, can help us get there.

Real-world data (RWD), of which provider-based data is a key component, is already used to precisely define the types of patients who would benefit most from a given therapy. Beyond simple measures of physical health, RWD can also provide a better picture of a patient's quality of life, productivity, and even financial security. Such insights can enable smarter R&D focus, more tailored clinical trial design, clearer value messaging to payers, and better-informed healthcare decisions. For example, leveraging RWD during clinical development can avoid costly trial recruitment delays by linking patients of interest to specific sites of care. In addition, RWD can be used to develop and implement synthetic control arms, which reduce the number of patients needed to conduct clinical studies and ensure that all recruited patients potentially benefit from an experimental therapy through the trial's treatment arm. Finally, by building precise value messaging based on RWE, the industry can maximize access and affordability to ensure that ▶

What if...

▶ those patients most likely to benefit from a given therapy are able to receive it.

These types of innovations would not be possible without health outcomes data from provider records. Continued progress down this path is critical and requires greater collaboration between the stakeholders creating life-saving therapies and those at the helm of delivering care to patients.

WHAT IF ... AI AND AUTOMATION REDUCED THE COST OF PHARMACOVIGILANCE BY 90%?

UPDESH DOSANJH
Practice Leader, Technology Solutions, IQVIA

With regulators encouraging doctors to report more adverse events and patients sharing their stories online, pharmacovigilance (PV) data is compounding faster and from more sources than ever before. The push from regulators and industry bodies to generate more in-depth trend data is also drastically adding to the overall costs of PV reporting. Industry regulations have been cited by more than 50% of global life-sciences CEOs as a top disruptive business trend. PV departments are looking to mitigate these costs and manage the increasing complexity of PV processes.

Traditionally, PV departments have resisted rapid technology changes, fearing loss of control within a highly regulated industry. However, with more than 70% of PV spending being on case processing, the adoption of AI and AI-supported automation has been seen as necessary for reducing these costs and freeing money for more data analysis and staying ahead of new regulations. Results from this drive for new methods have been variable due to most vendors' limited industry knowledge and the adoption of inappropriate AI models from nonclinical industries. As companies with deeper experience enter the market, it is only a matter of time before we radically change PV cost structures. The focus has been to reduce case processing costs, but little if any effort has been invested into leveraging new technology in the complex areas of data analysis and risk assessment, which is the real promise of AI.

Imagine being able to Google the entire history of your PV data and access meaningful results without any training. As precision medicine becomes the new standard for treatment, the ability to derive precise and rapid insights from your data will be mandatory. This is the real promise of AI-enabled PV.

WHAT IF ... LONGITUDINAL RECORDS PLAYED A ROLE IN PRESCRIBING?

MICHELLE HOISETH
Chief Data officer, Parexel

Imagine if we could create longitudinal patient records that allowed us to develop clinical data sets for therapies from clinical development into the prescribing environment? By making this reality, drug development processes as well as the patient experience could be transformed for the better.

WHAT IF ... CLINICAL TRIALS WERE IN-SOURCED?

SURESH KATTA
CEO, Saama Technologies

The pharma industry must take control of its own future, and learning to in-source clinical trials would be a monumental step toward self-directing that future. Since the pharma industry began outsourcing clinical trials, the average number of years for drug development has gone up tremendously, and the costs have skyrocketed to billions from millions. By in-sourcing clinical trials, the majority of the pharma workforce would have an opportunity once again to interact directly or indirectly with the patients for whom they are developing drugs. There is an opening for the pharma industry to embrace the technology that would allow it to in-source clinical trials and have the tech leaders report up to the C-suite. Many other industry segments have already taken this path successfully. By in-sourcing and intertwining with the technology innovation curve, the pharmaceutical industry can minimize first, and then slowly eliminate the age-old, laborious, erro- ▶

20 for 2020

11. What would it take to bring humanity back to healthcare?
12. How can we achieve an equitable healthcare system?
13. What if Apple/Amazon/Google bought a pharma company?
14. Will data scientists be the key to the future of the pharmaceutical industry?
15. What metrics can be used to hold companies accountable for D&I?
16. What if funding novel ideas was more equitable?
17. What can pharma do to win back public trust?
18. How can the next generation be inspired to join the industry?
19. What if innovation were embedded into every organization's culture?
20. What would be the impact on the industry — R&D to commercialization — if companies moved beyond the AI pilot phase to full adoption for decision making?

What if...

neous, time-consuming manual procedures for running clinical trials. With the right education and obvious incentives, technology-driven, newly discovered and simpler automated processes can accomplish a number of critical goals, including recruiting patients at the right levels in a timely fashion, designing better protocols with cognitive systems, validating study feasibility through clinical neural networks, conducting long drawn-out Phase I, II and III trials digitally, and fulfilling regulatory requirements through modernized applications.

WHAT IF ... ECLINICAL SOLUTIONS PROVIDERS OFFERED THEIR TEAMS ONGOING OPPORTUNITIES TO COLLABORATE AND CREATE NEW TECHNOLOGIES WITHOUT CORPORATE MANDATES OR REGULATORY RESTRAINTS?

CINDIE KAZMER

Senior Director, Project Management, Cenduit LLC

The industry should establish a creative forum for innovation and personal growth, we call it a hackathon, which provides the freedom to explore without having to adhere to preconceived notions about how the technology must be used. By giving development teams the license to innovate, a hackathon creates camaraderie and creativity as teams form to develop solutions and proofs of concepts. The ideas and data that emerge from a hackathon can inform development direction and become a part of a company's future development calendar. Ultimately, these innovations can lead to incremental changes as well as breakthroughs that have the potential to result in better site experiences, and better patient outcomes.

WHAT IF ... THE PROMISE OF PERSONALIZED MEDICINE WAS REALIZED?

PETER KEELING

CEO, Diaceutics

Pharma stands to profit by putting value back into its precision medicine commercialization efforts. Doing so starts with understanding the transformative partnership between optimized testing and better treatment outcomes. Appropriately investing early on in the timely incorporation of better testing into everyday clinical practice may lead to better testing/better treatment/better return on investment (ROI). This requires that pharma include funding in drug-launch budgets for the launch and awareness promotion of tests associated with a target therapy. History has shown that pharma still gains a meaningfully superior market share for therapy when brands promote and invest in the diffusion of a particular improvement in testing whether competitors benefit. For example, within the immune-oncology (IO) space in non–small cell lung cancer, Merck's Keytruda has clearly benefited from embracing this type of "better testing, better treatment" promotion to great competitive effect versus other IO therapies launched at the same time. In this way, pharma maximizes patient reach — and patients benefit with better health outcomes. The financial rewards for pharma have been documented, amounting to as much as $30 to $60 of additional treatment — otherwise lost — for every $1 invested in testing.

Given that at least one-third of patients are still missing out on therapy, we believe there is equal to or greater value, expressed in patients/outcomes and health economics in improving the diagnostic journey for cancer patients than in the introduction of a new smart therapy alone. Together, they are transformative. And given the dominant economic focus on better therapy, without a balanced focus and investment on improving the real-world testing ecosystem, the promise of precision medicine remains unfulfilled.

WHAT IF ... THE FEDERAL GOVERNMENT MADE MARIJUANA LEGAL?

DR. WILLIAM LEVINE

Founder and Chief Scientific Officer, CannRx

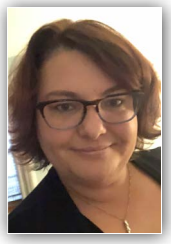
The federal government will inevitably develop a system to legalize cannabis. The industry is too large and affects too many people to remain solely as a state-based system. There are many different scenarios in which this may take place. The National Cannabis Industry Association (NCIA) is promoting a hybrid system that combines the pharmaceutical, dietary supplements, cosmetics, and alcohol regulatory systems. The NCIA refers to this novel concept as "de-scheduling" and it creates a completely new concept track for cannabis. Clearly, the government is concerned about a number of factors; safety, efficacy, quality of the products as well as false marketing or unsupported claims to the consumer. One of the overriding issues that the cannabis industry is grappling with is that of isolated cannabinoids. There is extensive data and many decades of ethnobotanical use of cannabis to provide a reasonable profile of safety. But if we increase the concentration or isolate single cannabinoids, we can no longer rely on that database to provide safety data. It is a simple concept; if you change the substance, both the pharmacologic effect and the toxicity profile can also change.

I believe that the federal government will use the existing agencies, FDA and FTC, to monitor cannabis, but will slightly modify the program to accommodate the existing industry.

WHAT IF ... WE COULD DIAGNOSE MENTAL HEALTH MORE ACCURATELY?

ANTONY LOEBEL, M.D., President and CEO, Sunovion Pharmaceuticals

Imagine if we could improve quality of life for patients with various mental health conditions by diagnosing more accurately using new technical advances and finding novel therapeutics that actually change the course of illness over time.



WHAT IF ... HUGE DATA SETS COULD UNLEASH HUGE REWARDS?

MICHELLE MARLBOROUGH

Chief Product Officer, AiCure

The organization and structuring of data is a constant challenge in our industry. It was not too long ago that aggregating data across studies was a huge amount of effort. The realization that data standards were important started to solve that problem, until the volume of data available to us sky rocketed.

We now have the ability to amass exabytes of data, if we so desire. Our technological ad- ▶

What if...

vances continue to enable the development of these data lakes, moving us away from needing to make strict upfront decisions around how data should be structured and managed. There are important concepts that can be taken from our past attempts to standardize, most notably, that early data standardization was prioritized around understanding the use and context of the data. This key principle should be reapplied now. We need to have a clear goal or strategy for the data that is being collected. In the simplest terms, a question to be answered will ensure that the focus becomes on collecting the right data to solve the problem, not just collecting data for the sake of collecting data, which might as well be called data hoarding.

WHAT IF ... PATIENTS WERE THE ULTIMATE DECISION-MAKERS IN THE DRUG DEVELOPMENT PROCESS?

SY PRETORIUS
Executive VP, Chief Medical & Scientific Officer, Parexel

This simple idea could impact many aspects of drug development. For example, patients would own their personal health data and decide where and how it could be used to develop new drugs. Likewise, information about clinical trials would be easily accessible and patients could access this information via their mobile phones. Endpoints would be selected based on what patients cared about most, supporting the development of therapies that make a difference in patients' lives.

WHAT IF ... WE PUT THE SAME CARE AND INVESTMENT INTO INTEGRATING AND SUPPORTING CLINICAL DEVELOPMENT TEAMS AS WE DO IN INTEGRATING ECLINICAL TECHNOLOGY SYSTEMS?

BRENDA REESE
Founder and President, phaseUP

Most trials are run by a mix of internal and external groups. Making sure the overall team is cohesive, collaborative, and communicating before the program starts can make the difference between a trial that runs smoothly and one that needs a rescue, or fails.

WHAT IF ... MILLIONS COULD BE RELEASED FROM THE BURDEN OF ANXIETY AND DEPRESSION THEY BATTLE EVER DAY?

SHAWN SINGH
CEO, VistaGen Therapeutics

Anxiety and depression are overwhelming more than 20 million Americans every day. The global scourge of these debilitating disorders exceeds 300 million. We have a critical need for new therapeutic solutions for those struggling with these cruel disorders. Breakthrough medicines that are fundamentally different from current treatments are a key part of the new solution paradigm. To complement "talk therapy," patients need faster-acting medicine that can be taken at home (not in a clinic), without risk of addiction, hallucinations, sedation, or other side effects and safety concerns.

The emerging use of ketamine for depression is an example of out-of-the-box thinking by pharmaceutical researchers. Ketamine, widely used for anesthesia since 1970, was long overlooked as a solution for depression due to its dissociative effects and abuse potential. Now, ketamine's rapid antidepressant effects in treatment-resistant patients has captured the global spotlight, enhanced by the FDA's recent approval of a nasal spray formulation called Spravato. Ketamine therapy must be administered and monitored in a clinic. While, ketamine offers hope for millions who do not benefit from standard antidepressants, we now need to go beyond ketamine to fast-acting antidepressants that can be taken at home, without ketamine's side effects and safety concerns.

WHAT IF ... WE BROKE THE SILOS THROUGHOUT PRE-COMMERCIALIZATION TO POST-COMMERCIALIZATION?

GREG SKALICKY
Chief Revenue Officer, Eversana

If we think about all the services and solutions that touch a newly launched brand in the market, we can all agree that innovations in therapeutic development have advanced beyond traditional product launch strategies and service models. In every step of the product lifecycle, we see pockets of transformation. And the problem is exactly that — "pockets" of transformation. The pipeline in regenerative medicine, for example, is focused on the complexity of pricing, which it must, but what about logistics — everything from chain of custody to temperature monitoring — and the risk that comes along the supply chain through patient support?

Pockets of innovation may address these concerns, but to effectively launch a product — from clinical research to trials, to in-market, to post-commercialization — I argue that traditional service silos stand in the way of true healthcare transformation. Ask yourself, do disparate service providers look at the lifecycle in the same way you do? Do they understand how everything from pricing and payer outreach informs the 3PL, specialty pharmacy, hub, and pharmacovigilance solutions? Let's break down these traditional service silos to create a seamless patient experience that's strong enough to withstand loss of exclusivity or competing products. This innovation and vision supports integrated solutions that put the patient at the center, because when we do, patients get access to efficient, effective, and innovative healthcare.

WHAT IF ... WE LIVED IN A WORLD WITHOUT DISEASE?

BEN WIEGAND, PH.D.,
Global Head, World Without Disease Accelerator, Janssen

We hope to make disease history such that it is read about in history books versus experienced by family members, friends, and loved ones. Through the elimination of disease, the focus becomes maintenance of health and ensuring an active, healthy lifespan.

FOR BONUS CONTENT USE YOUR QR CODE READER OR GO TO bit.ly/PV1119-WhatIf

What if ...

WHAT IF ... HEALTH ECONOMICS AND OUTCOMES RESEARCH INFORMED EVERY HEALTHCARE DECISION?

NANCY BERG

CEO and Executive Director, ISPOR—The Professional Society for Health Economics and Outcomes Research

Health economics and outcomes research (HEOR) has grown in importance and influence due to the rapidly rising costs of healthcare and the desire to optimize health outcomes for patients where multiple treatment options exist. However, HEOR and evidence-based decisions are not yet ubiquitous. A vision that many HEOR experts share is a world where every patient benefits from evidence-based, shared decision making. Multidisciplinary experts in HEOR understand that outcomes research combined with health economics provides vital information to healthcare decision makers from the patient intervention to the healthcare system level. While both health economics and outcomes research can be performed in isolation, the synergy of combining the right data (outcomes research) with thoughtful (health) economic analyses based on multiple stakeholder perspectives ensures that even complex healthcare questions can be evaluated rationally. Paying for value requires first defining what value is and to whom that value matters — what perspective, measuring the care delivered in real time, and feeding that information back into the system so adjustments can be made to incentivize and reimburse high-value care appropriately. Imagine, if ideally every patient received the treatment that provides them with the best possible health outcome? Healthcare providers have clear information on how to treat their patients for optimal outcomes and with therapies that patients can afford. Health technology developers have the info they need to develop effective and innovative therapies that patients can access. And payers have the evidence that allows them to effectively and efficiently treat their patient population to provide optimal health outcomes within their defined budgets. We have a way to go, but many HEOR professionals see a near future where the field of HEOR can infuse every area of healthcare decision-making and evolve toward true learning healthcare systems.

WHAT IF ... IN 2020 SPECIALITY DRUGS PRESCRIBED NEED TO HAVE AN ACCOMPANYING DIGITAL COMPANION?

JENNIFER BUTLER

Chief Marketing Officer, Medisafe

Having a digital therapeutics solution to accompany the drug used to be a nice to have. This is no longer the case — patients, payers, and providers are all demanding a digital solution to manage the patient journey — and a digital therapeutics companion is now the table stakes in 2020. Patients expect digital support to manage complexities, especially when left to their own devices to manage, which is exactly what happens with speciality pharma drugs.

Patients often see multiple HCPs, undergo numerous procedures and their drug treatment regimen could be quite complex, often involving multiple medications taken in an on/off cycle. When patients are prescribed medications, their prescriptions are typically sent to a specialty pharmacy, which is a concept most people are not familiar with. It's a frustrating experience for patients who often have to place numerous calls in order to figure out where their prescriptions were sent and when they will receive the medication, which can cause additional anxiety. By the time the medication arrives, patients are likely to have forgotten the instructions and counseling they received when they saw their medical provider or spoke to a pharmacist. In addition, patients often go from not taking any medications to having to take multiple drugs, which can be overwhelming. Today, we live in a world that strives toward personalization in medicine. What's needed to help patients with chronic complex conditions is continual support and personalized, targeted interventions. Digital drug companions provide continual support to patients through therapeutically designed AI and a direct connection into care teams at critical times.

WHAT IF ... EVERY PHARMA COMPANY HELD ITSELF ACCOUNTABLE FOR DELIVERING HEALTH OUTCOMES BY DEVELOPING PRODUCTS AND SERVICES THAT TRULY MEET THE NEEDS OF PEOPLE LIVING WITH CHRONIC HEALTH CONDITIONS?

OLIVIER CHATEAU

Co-Founder and CEO, Health Union

If the industry honestly and earnestly considered this question, there would be more balanced and transparent information about treatment options, provided in a fair and realistic way for people of various financial means to access care. On the research and development level, more patients could consider clinical trials as a treatment option to accelerate development of new therapies. On the commercial level, companies would ensure the patients they're reaching are those who have the best opportunity to benefit from their treatments.

WHAT IF ... GENE EDITING CHANGED THE WORLD?

DR. ANDRE CHOULIKA

CEO, Cellectis

The most important thing about gene editing is that we've barely scratched the surface in asking how this could change the world. Gene editing is still at its therapeutic debut and it can be difficult to predict how the performance of these therapies will evolve over the next few decades. What's exciting is that in a short amount of time we have seen a sharp acceleration in the performance of these technologies and an increase in the number of academic researchers who are exploring this field thanks to the accessibility of tools such as CRISPR. As the technical performance of gene editing matures, new genetic diseases will be treated. In a few decades, this could represent hundreds of orphan diseases. We are only at the beginning of this journey, and it is important that we continue to ask how we can further innovate for the oppor-

What if ...

tunity to improve the quality of life for millions of patients and their families.

WHAT IF ... THE INDUSTRY ACHIEVED DATA INTEROPERABILITY?

THOMAS DUDNYK
President, VIVO Agency

We've been talking about data interoperability for 20 years now, and our failure to achieve it is exacting a huge toll. For starters, data-driven care-transformation initiatives are extremely difficult to lead when data sets are incomplete. Super powerful clinical decision support (CDS) tools can notify physicians of the best lab, pharmacy, and radiology orders based on clinical evidence in real-time. With full data sets, CDS could tackle the colossally wasteful and positive-outcome-impeding problem of service overutilization and clinical variation. Lack of interoperability also makes it hard to coordinate care — a big reason we waste billions every year on unnecessary ED visits and readmissions. Finally, it also stifles innovation, which, as a result, now takes place almost entirely on the periphery in low impact, niche areas. To make meaningful, structural advances, we need to liberate data from its database silos and normalize it, so it can be accessed, shared, and measured. This won't happen until Congress mandates it and the data monsters, for example Epic and Cerner, make it easy to access. Only then will the data analytics powerhouses of Google, Amazon, and Apple swoop in and get meaningfully engaged to disrupt healthcare.

WHAT IF ... EVERYONE SEQUENCED THEIR GENOME?

DAVID FISCHER, PH.D.
Executive Director Discovery Sciences, Scientific Advisory Services, Charles River

This is actually already happening, with patients and families getting full genome sequencing done and analyzed, outsourcing the discovery, development, and manufacturing of personalized therapies at CROs and working with the FDA to allow the patient to be dosed by their own drug, all supported by crowdfunding. This clearly solves an unmet clinical need, but how scalable it is remains to be seen.

WHAT IF ... PERSONALIZED MEDICINE BECAME A REALITY?

DON GABRIEL, M.D., PH.D.,
Senior Director, Medical Oncology and Scientific Strategy, UBC

The goal of personalized medicine is to select the best possible treatment regimen at appropriate drug doses for a specific patient. These criteria are necessary to assure optimal regimen efficacy, minimize patient toxicity, provide the best possible patient outcomes, and minimize pharmaco-economic stress. To that end, mutational analysis of tumors has made great strides in selecting treatment regimens for molecular targeting for cancer patients. Of equal importance is the patient's ability to metabolize the drug adequately. One way to view how patients metabolize drugs is to divide them into three basic groups: rapid, normal, and slow metabolizers. Rapid metabolizers may quickly clear the drug so that its efficacy is diminished. Slow metabolizers may lead to accumulating the drug that can lead to increased toxicity. Thus, these metabolic parameters should influence the regimen selection and the dosing of the drug to assure both efficacy as well as safety. Further, patients with certain polymorphisms in Cytochrome P450 (CYP450) enzymes may not activate prodrugs resulting in little or no efficacy. For example, Clopidogrel (Plavix) is a prodrug, and CYP2C19 is the major enzyme involved in the conversion of clopidogrel into an active metabolite. Individuals who carry two non-functional copies of the CYP2C19 gene are classified as CYP2C19 slow metabolizers. And these patients have little to no enzyme activity and cannot activate clopidogrel via the CYP2C19 pathway, which means the drug will have no effect. So future optimal medication therapy management should include an assessment of the patient's ability to metabolize the drug. And in cancer patients, this assessment should be done along with the mutational analysis of tumors.

WHAT IF ... REWARDS FOR CLINICAL DEVELOPMENT WERE ALLOCATED DIFFERENTLY?

CHRIS GARABEDIAN
Chairman and CEO, Xontogeny

The biopharmaceutical profession is a unique industry in that it survives with an overwhelming track record of failure. Even if we assume a good year of FDA approvals at 50, this would be about 1,000 product approvals during a 20-year time frame. In reality, the number of NME and BLA approvals over the last 20 years (1999-2018) totaled 600. A 2016 PhRMA report identified more than 17,000 unique preclinical and clinical development candidates with approximately 8,000 private and public biopharmaceuticals companies in the BioCentury/BCIQ database listed as developing therapeutic drug technology. Given the last three years have seen unprecedented investment in the biopharmaceutical sector, it is likely that there are far more than 17,000 unique drug candidates now in development. Even if one applies a very conservative estimate that there have been five times this number over the last 20 years, it would suggest that 85,000 drug candidates that were identified and tested, at least in preclinical models, yielded 600 FDA drug approvals meaning fewer than 1% of preclinical candidates led to an FDA approval. So, who would be the most well-paid free agents in the pharmaceutical industry? The chemist who was attached to inventing molecules that led to FDA approval? The biologist and translational medicine expert who identified the right disease application that led to FDA approval? The clinical trial design expert who understood the disease, competitive landscape and regulatory requirement to shape the appropriate study design to enable a robust signal of efficacy? The clinical pharmacologist who called the right dose, formulation and regimen that led to clinical success? The biostatistician who employed the right statistical design,

What if ...

method and powering that led to a statistically significant outcome? And the medical affairs and commercial representatives who were able to outperform in a marketplace, especially with undifferentiated competition?

WHAT IF ... HEALTHCARE LITERACY WAS PART OF EARLY EDUCATION?

DEBORAH LOTTERMAN

Chief Creative Officer, precisioneffect

What if serious health literacy was a requirement for graduating from high school? This includes how to evaluate a clinical trial and how to talk with an insurance company without losing your cool.

WHAT IF ... EVERY PATIENT'S CLINICAL TRIAL EXPERIENCE CONTRIBUTED TO COLLECTIVE LEARNING?

MIKA NEWTON

CEO, xCures

The traditional way of doing clinical trials involves finding the best patients for a given therapy. A new approach would leverage knowledge, with AI support, to find the best treatment for each patient. From these treatments, whether successful or not, all patients would provide a systemic learning opportunity that is captured as real world data and generate real world evidence. We can see steps in this direction with the Global Cumulative Treatment Analysis (GCTA), particularly toward the vexing issue of treating cancer. Under Internet-operated GCTA coordination, all patients would be monitored and treated based on the best available knowledge. When there is uncertainty about whether a treatment will be beneficial, a decision algorithm — a combination of human and AI — assigns treatments to patients as a set of balanced options, and then calculates system-wide information-gain among that set of options. Importantly, because the set of options is created before the information-gain calculation, the welfare of the individual patient is not subjugated to the needs of society. Teams of experts and algorithms will enable GTCA to efficiently coordinate the thousands of treatment decisions made daily across the whole medical system, in theory delivering the best possible treatment to every patient.

WHAT IF ... THE CANCER LANDSCAPE MOVED TOWARD DEVELOPING SUSTAINABLE CARE FOR PATIENTS?

DANIEL O'CONNOR

President and CEO, OncoSec Medical

While immunotherapies have changed the way cancer is perceived and treated, current immunotherapies still face many challenges, including improved effectiveness and patient response rates. Today, the majority of patients do not see benefits from marketed immunotherapies, such as checkpoint inhibitors. We are working to address this unmet medical need by focusing specifically on anti-PD-1 nonresponder patients. Our R&D also remains committed to sustainability. We are committed to creating a highly scalable platform with inexpensive manufacturing costs, potentially offering an innovative treatment option well below the costs of other biologic drug therapies. By doing so, we are bridging the treatment gap for patients while ushering in a novel and sustainable approach to fighting cancer.

WHAT IF ... PATIENTS HAD MORE SAY?

ANSHAL PUROHIT

President, Purohit Navigation

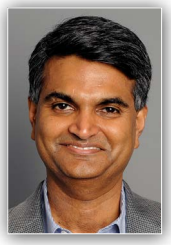
What if "customers" had more skin in the "game," and therefore more "say" in what therapies are brought to market and/or in what "clinical success" looks like.

WHAT IF ... HEALTHCARE SYSTEMS EMPLOYED SYSTEMWIDE CONTINUOUS LEARNING?

DAN RHODES

Co-Founder and CEO, Strata Oncology

Rapid progress in oncology requires we learn as much as we can from each patient, including the molecular makeup of the patient's disease and about treatment outcomes. Current approaches fail to deliver system-wide tumor molecular profiling and low-cost IT strategies to capture treatment outcomes for all patients. One solution is to deploy an observational genomic sequencing protocol systemwide to enable universal patient access tumor molecular profiling and efficient collection of standardized outcome metrics in an anonymized central database. This model would drive better outcomes by delivering the most appropriate approved and investigational therapies to patients based on clinical and molecular features of disease. It would accelerate cancer drug development by providing clinical and genomic data to catalyze new insights and solve a systemic challenge in precision drug development by increasing the patient population that can be screened for precision trials. Finally, it can advance value-based cancer care by providing data to perform comparative effectiveness research.



WHAT IF ... THE PHARMA INDUSTRY USED THE POWER OF DATA TO IMPROVE THE YIELD AND THROUGHPUT OF THE CLINICAL DEVELOPMENT PROCESS?

NAGARAJA SRIVATSAN

Chief Digital Officer, R&D Solutions, IQVIA

Pharma companies have access to an unprecedented amount of data. There is a large amount of research on bio-models on how the body functions. There is good scientific insights on building disease models based on RWD/RWE. To improve the yield of the clinical development process, so that more successful drugs are launched, pharma needs to aggressively adopt an in silco approach. Insilco models will help us find out how the drug functions, its safety profile, and finally potential markers that can help us recruit the right patients, and increase the likelihood of success.

MARKET VALUE

TOP 10 PHARMA COMPANIES COMBINED >

PHARMA BRANDS

The top 10 most lucrative drugs in 2018 were worth approximately $87 billion.

$87 billion 2018

GENE THERAPIES

CAGR 36.52%

The global cell and gene therapy market was valued at $1.07 billion in 2018 and is projected to grow to more than $8.95 billion by 2025, for a CAGR of 36.52%.

2018 2025

TREATMENT TO PREVENTION

A New Healthcare Model

HEALTH EQUITY

Blacks, American Indians, Alaska Natives (AI/ANs), and Native Hawaiians/Pacific Islanders (NHPIs) received worse care than Whites for about

40%

of quality measures.

SOCIAL MEDIA INFLUENCERS

87% of people who viewed information shared by an influencer about a specific drug would ask their doctor or healthcare provider about it.

BRINGING HUMANITY TO HEALTHCARE

5% less than 9 mins. | 22% 9-12 mins. | 29% 13-16 mins. | 33% 17-24 mins. | 11% 25 mins. or more

TIME U.S. PRIMARY CARE PHYSICIANS SPENT WITH EACH PATIENT

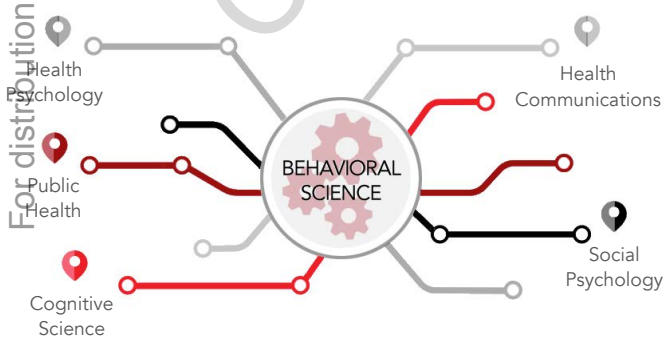
WEARABLES

The global wearable medical device market is expected to reach a market value of **$27.26 BILLION** by

2023

BEHAVIORAL SCIENCE

Research conducted for decades by health systems and academic groups demonstrates how to change behavior and improve outcomes.



INTERNET OF THINGS

$534.3 billion

CAGR 20.2% (2016-2024)

534.3

2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025

FUTURE WORKFORCE

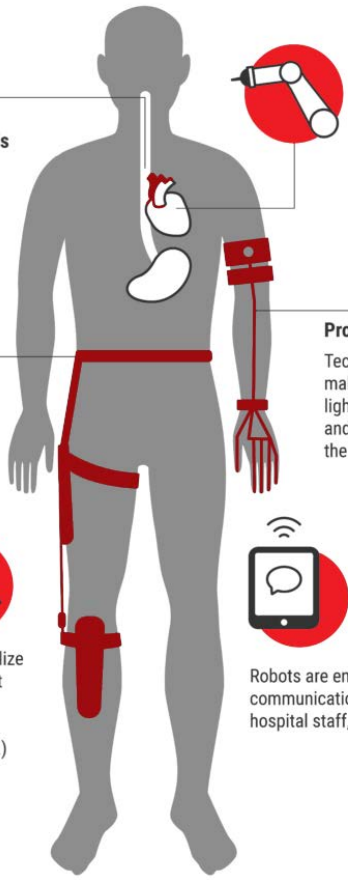
Millennials will form

50%

of the global workforce in 2020.

HEALTHCARE ROBOTS

How Robotics Is Changing The Face Of Medicine



Microbots & Diagnosis

Remote controllable camera-equipped microbots can be safely swallowed by patients to help doctors diagnose conditions.

Minimally Invasive Surgery

Robotically-assisted surgical devices can help surgeons make less invasive incisions and perform more precisely in smaller spaces.

Prosthetics

Tech advances are making bionic limbs lighter, more affordable, and more connected to the human brain.

Rehabilitation

Rehabilitation robots can help injured or immobile patients begin robot-aided recovery exercises sooner.

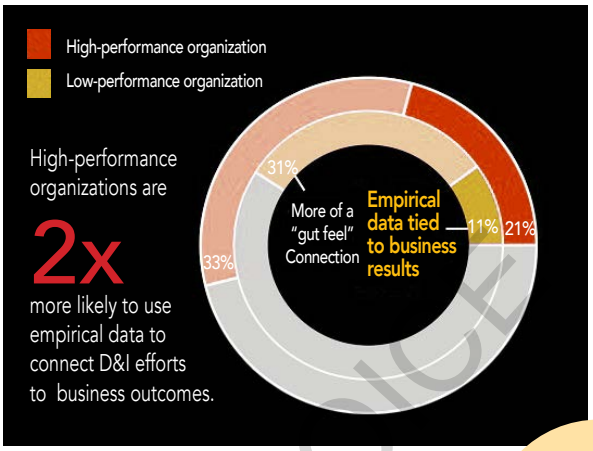
Hospital Sterilization & Delivery

Robots in hospitals can sterilize environments to help prevent infections as well as make routine deliveries (supplies, medications, paperwork, etc.) to give staff more time to focus on patients.

Telemedicine & Communication

Robots are enabling better remote communication between doctors, hospital staff, and patients.

D&I METRICS



GENE SEQUENCING

36 milllion 2030

More than 36 million rare disease patients will have their genomes sequenced by 2030.

DATA SCIENTISTS

- Predominantly male (69%)
- 8 years in the workforce overall
- Bilingual
- Python/R (73%)
- 2.3 years as a Data Scientist
- Master/PhD (74%)

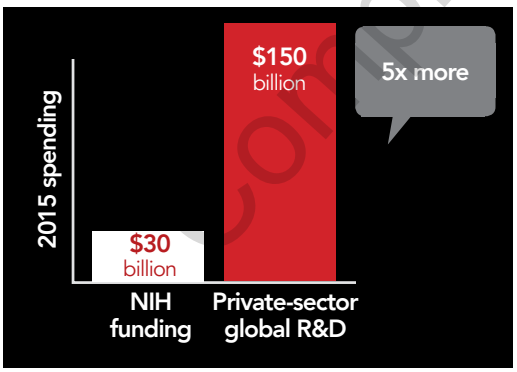
TOP INNOVATIVE PHARMACEUTICAL COMPANIES

1. Gilead Sciences
2. AbbVie
3. Eli Lilly
4. Pfizer
5. Merck & Co.
6. Sanofi
7. Novo Nordisk
8. Roche
9. Novartis
10. GSK

ARTIFICIAL INTELLIGENCE

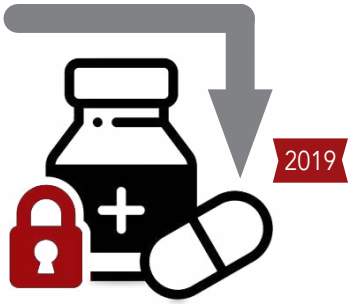
The TOP 10 PHARMA COMPANIES have all collaborated with or acquired **AI TECHNOLOGIES**

FUNDING



PHARMACEUTICAL INNOVATION

The pharmaceutical industry has unseated the federal government as the **LOWEST-RATED** industry this year.



DECENTRALIZED TRIALS

- **50 mi** average distance patient lives from nearest site
- **<5%** of patients participate in clinical research
- **49%** of participants drop out before study completion
- **48%** of trial sites miss enrollment targets

PUBLIC TRUST