2019 LIFE SCIENCES INDUSTRY TRENDS

CLARKSTON CONSULTING

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The life sciences sector is inherently complex, operating under different pressures and influences compared to other industries. While the industry as a whole is often accused of being slow to adapt to change, 2018 saw a concerted focus to address past mistakes and adapt to the modern healthcare landscape.

Some trends, such as efforts to disrupt pricing models, have yet to gain significant traction but precedents have been set indicating the rise of value-based models. Meanwhile, organizations are investing heavily into therapeutic innovations in gene therapy, cell therapy, diagnostics, and biomarker testing. Life sciences organizations also continue to explore the utility of AI, machine learning, and blockchain technology to augment standard models and processes.

Below, we discuss in depth the critical trends playing a role in shaping the life sciences industry in 2019. Leveraging our experience in this space, we aim to point out where leaders can position themselves to take advantage of new opportunities.

ADMINISTRATION PRICING EFFORTS NOT GAINING MUCH TRACTION

In 2018, anyone reading a headline or following the evening news caught the high-profile buzz surrounding drug pricing. Most notably, in July, President Donald Trump attacked Pfizer's pricing strategy on Twitter, shaming the company for "merely taking advantage of the poor and others unable to defend themselves, while at the same time giving bargain basement prices to other countries in Europe & elsewhere." In response to the president's tirade, Pfizer agreed to postpone its pricing increases, while its peers similarly tempered price increases. Despite the headlines, the pricing back-and-forth has not yet yielded decisive action for either manufacturers or the federal government.

"Requests and public shaming haven't worked [to lower drug prices]," said Michael Rea, chief executive of RX Savings Solutions, a company that helps health plans and employers seek lower cost prescription medicines.

As the pricing debate continues into 2019, many are wondering how legislators will respond and whether or not more stringent pricing policies are coming. In 2018, the Trump administration attempted to make good on its pledge to lower the cost of prescription drug prices, proposing a rule requiring drug companies to give list prices for their products in television ads. As regulators and legislators continue to explore direct efforts for addressing pricing, there have also been more ancillary efforts, such as increasing the availability of generics.

For 2019, it's clear that the pricing debate isn't going away anytime soon. Drug manufacturers must be proactive in educating and collaborating with regulators and legislators to provide understanding of medical costs while exploring innovative, non-traditional pricing plans. The pricing issue won't be solved through regulatory intervention alone, it will require a holistic view of the entire patient experience.

Generic Drugs

In 2018, U.S. Food and Drug Administration (FDA) Commissioner Scott Gottlieb promised to increase the availability of generic drugs. By October 2018, the FDA announced more approvals and tentative approvals for generic drugs in FY 2018 than it did in both FY 2017 and FY 2016. The 971 total, as compared to 937 in FY 2017, includes 781 final approvals and 190 tentative approvals. The efforts have been very effective, as, according to Gottlieb, “nearly 90 percent of the US drugs market is now compromised of off-patent products."

971
APPROVALS AND TENTATIVE APPROVALS FOR GENERIC DRUGS IN FY 2018

937
APPROVALS AND TENTATIVE APPROVALS FOR GENERIC DRUGS IN FY 2017

843
APPROVALS AND TENTATIVE APPROVALS FOR GENERIC DRUGS IN FY 2016

Compared to directly controlling prescription drug prices, incentivizing generic competition has shown to be a more cost-effective and taxpayer-friendly approach. With more generics on the market, prescription drug makers are now feeling the pressure to price competitively and keep an even more critical eye on looming patent cliffs. Further, end-consumers are feeling the benefits in their wallets whenever they visit the pharmacy counter. “With the average co-pay around $6, generic medicines are affordable, and patients benefit from lower costs and healthier lives. Generic competition works, producing nearly $2 trillion in savings and annual price reductions of 7 to 8 percent.”

The trend is projected to continue, as Gottlieb has been quoted saying, “Our work is not done. We’ll continue taking additional steps to help ensure patients have access to the drugs they need by making generic drug approval more efficient and predictable. We are doing this by continuing to streamline the generic drug review process to get more competitors on the market. We have found that having three or more generic competitors brings prices down more sharply than with only one or two generic competitors.”

For big pharma, it’s now more critical than ever to re-examine and re-evaluate future product and market strategies. With groundbreaking innovations in drug development in recent years, the rise of generics is not the death knell it once was for the industry. The inherent protection against generic alternatives in autologous and allogeneic therapies represents a significant strategic and competitive advantage for many drug makers. Pharma businesses can also utilize innovative combination products to drive greater market differentiation against generics.

GENE THERAPY READY FOR ITS CLOSE-UP

Gene therapy aims to address the root cause of a disease by precisely targeting defective genes. While it is still widely in experimental stages and complex across a myriad dimensions, there is massive potential for gene therapy. For this reason, companies are increasingly moving into this space, a paradigm shift holding the promise of cures rather than just treatments.

The FDA approved three gene therapies last year, and FDA Commissioner Scott Gottlieb recently said he expects 40 to be approved by 2022 — including, for example, a cure for sickle cell anemia within 10 years.

AveXis, acquired by Novartis Pharmaceuticals in May, hopes to become the second biotech with a marketed gene therapy, Zolgensma, in the U.S. Also in 2019, AveXis President David Lennon expects the gene therapy for spinal muscular atrophy — a debilitating disease affecting the spinal cord that can rob victims of the ability to walk, eat, and even breathe — to gain approvals in Europe and Japan. If successful, Novartis' AveXis would follow in the footsteps of Spark Therapeutics, which gained approval in the U.S. in late 2017 for a gene therapy that treats a rare eye disorder.

The tricky part about gene therapy should be no surprise to anyone - pricing. Some analysts have suggested gene therapy drugs could cost millions. The industry is still divided on pricing approaches for gene therapy. With even more therapies coming to the market in 2019, it's critical that pharmaceutical companies begin building value-based agreements into the medical ecosphere. Diagnostics will play a critical role in understanding therapeutic efficacy to develop value-centered pricing agreements. Through transparent, outcomes-focused collaboration with payers and other care stakeholders, strategic efforts should be focused to identifying and capitalizing on opportunities to drive down the total cost to the patient across the value chain.

$442

WORLDWIDE, THE GENE THERAPY MARKET IS EXPECTED TO REACH $442 BILLION BY 2023.

SOURCE

OFF-THE-SHELF CELL THERAPY

CAR-T therapy involves the infusion of T-cells specifically engineered to identify and kill cancerous cells. While it's speculated that various advanced CAR-T approaches will be approved by the end of this year, there are still lingering questions about the treatment's scalability and long-term potential. For one, removing T-cells directly from patients and engineering them in real-time is a time-consuming and resource-intensive process that companies like Novartis Pharmaceuticals and Gilead Sciences have alluded to regarding their treatments.

In comparison to pharmaceutical and biologic drugs, gene and cell therapies face unprecedented challenges requiring a complete shift from traditional supply chains. No "make-to-stock" inventory buffer will exist due to the therapy's personalized and perishable nature, driving tremendous complexity and difficulty across planning, manufacturing and distribution globally. Such a time-sensitive supply chain requires an extremely high degree of precision and the resulting high level of customer service, especially for patients with life threatening conditions.

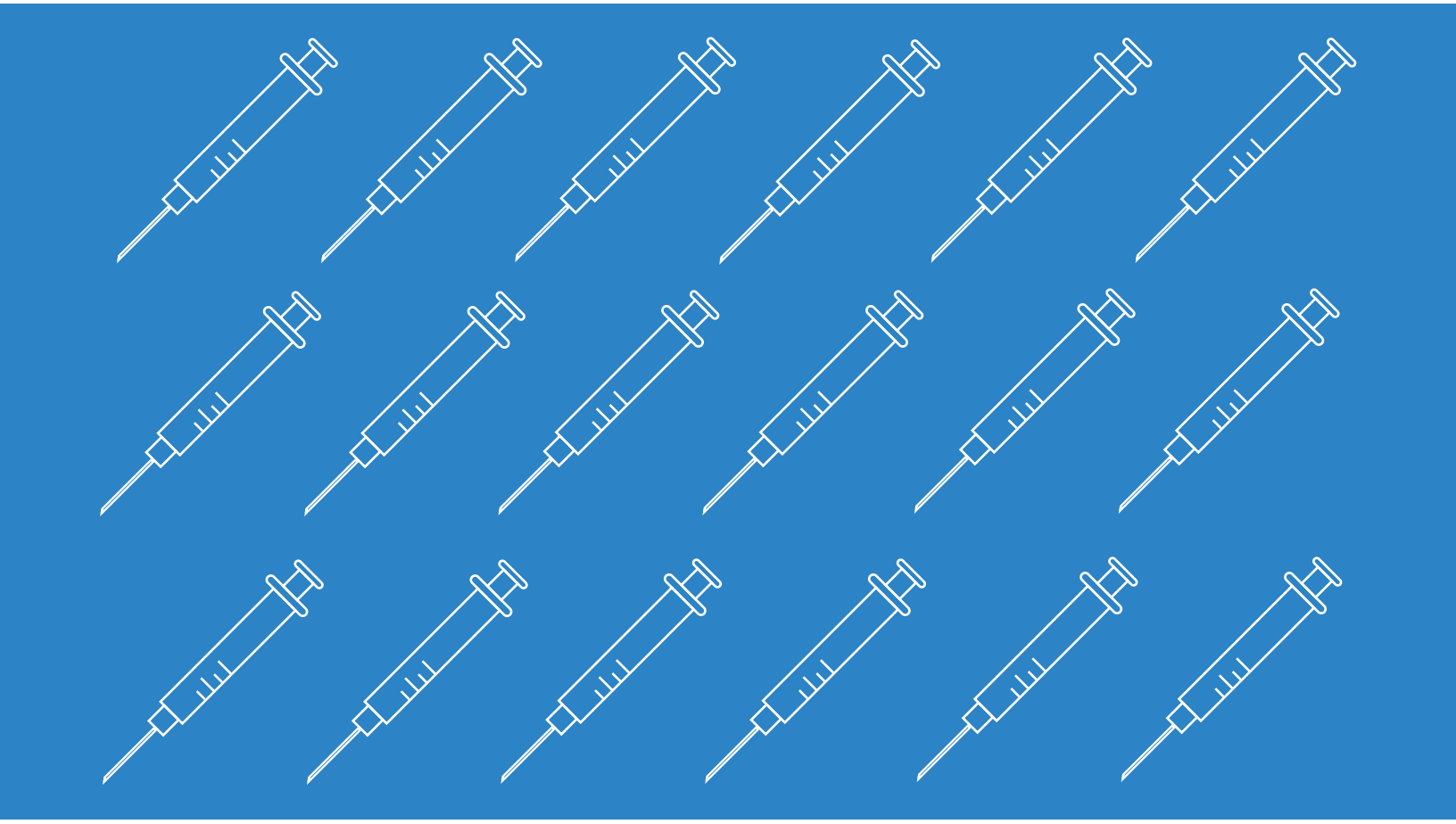
Furthermore, because autologous cell therapies are personalized with a batch size of one, the chain of custody and identity must be accurately maintained throughout the supply chain, no matter how complex. As such, personalized medicine requires a personalized supply chain with real-time visibility and control.

Seeing the hurdles associated with CAR-T, organizations are attempting to take the technology a step further by introducing allogeneic CAR-T therapy that instead incorporate cells from healthy donors. This new brand of "Off-the-Shelf Cell Therapy" aims to mass-produce cell products that are more predictably engineered and can be delivered more readily to treat more patients than traditional CAR-T.

The biotech company, Allogene, raised more than $400 million in private financing for their off-the-shelf technology before pulling off a $288 million initial public offering last month. In June, Precision Biosciences raised $110 million in private financing to take its off-the-shelf CAR-T into human trials.

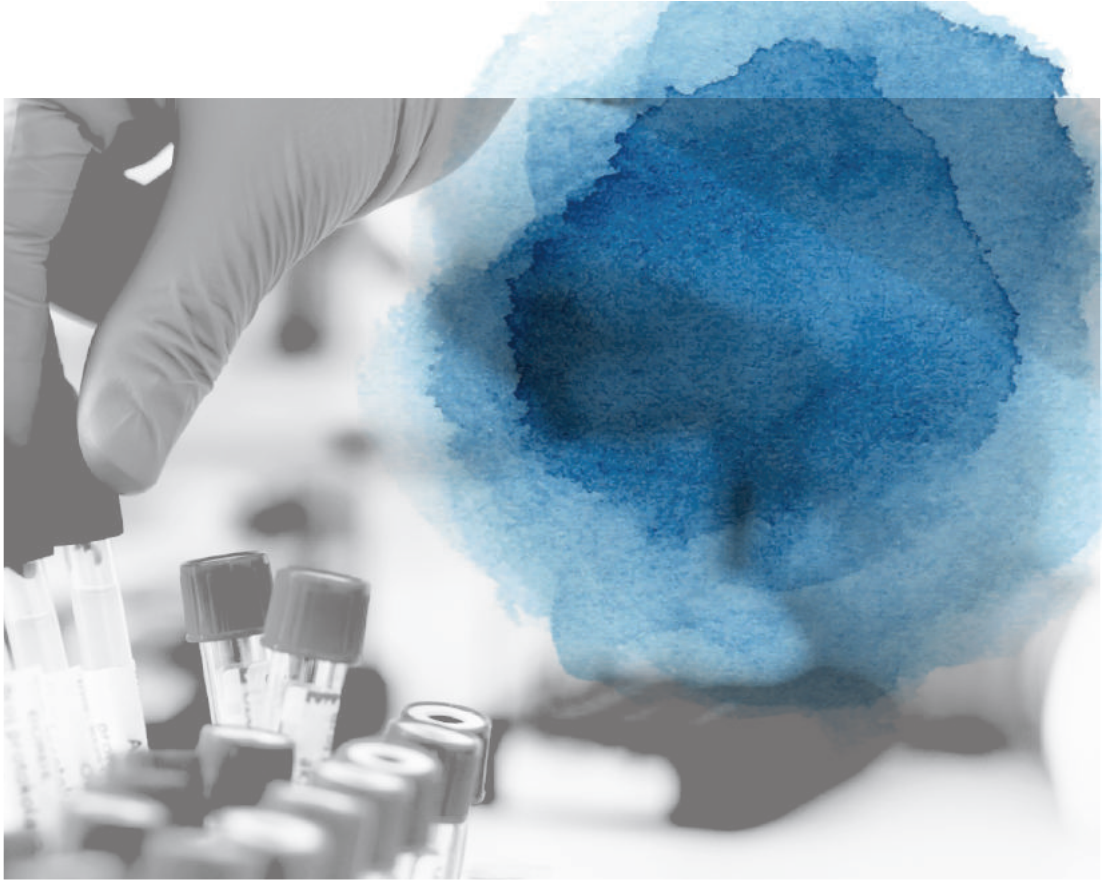
Maximizing patient treatment while minimizing total cost of ownership require a demand-shaping approach, an optimized supply network, and a seamlessly planned and flawlessly executed supply chain. With more approvals anticipated in the coming years, 2019 is the time when more companies will start to design, redesign, or create new supply chain models needed for personalized medicine. In addition to modifications to existing processes and systems, adoption of innovative strategies and digitalization technologies will play a large role. As organizations adapt their operating model, the commercial model will follow suit. Leveraging advanced diagnostics, organizations can better understand therapeutic impact and use the resulting data to enhance value-based pricing contracts. Furthermore, improvements to diagnostic capabilities will boost the industry's ability to bring the right off-the-shelf therapy to each patient.

Within the coming decade, off-the-shelf cell therapy will likely become a reality. Organizations that are keen on pursuing this opportunity will need to be cognizant of shifts to current standards and regulations. Only recently have cells begun to be viewed as products in and of themselves, so there will likely be changes to policy definitions and the specifics regarding how we treat cell-based products. From a patient and treatment perspective, off-the-shelf CAR-T could address some of the most difficult diseases, as the immune system can now be tweaked in ways it never has been before.



BIOMARKER TESTING

Investment in tools, technologies, and resources related to biomarker testing will allow cell and gene therapy makers to better understand their patient populations and the impact treatments may have. Biomarker research can and will have significant impact to how treatments are developed and administered, empowering life sciences companies with even more data to improve safety and efficacy.



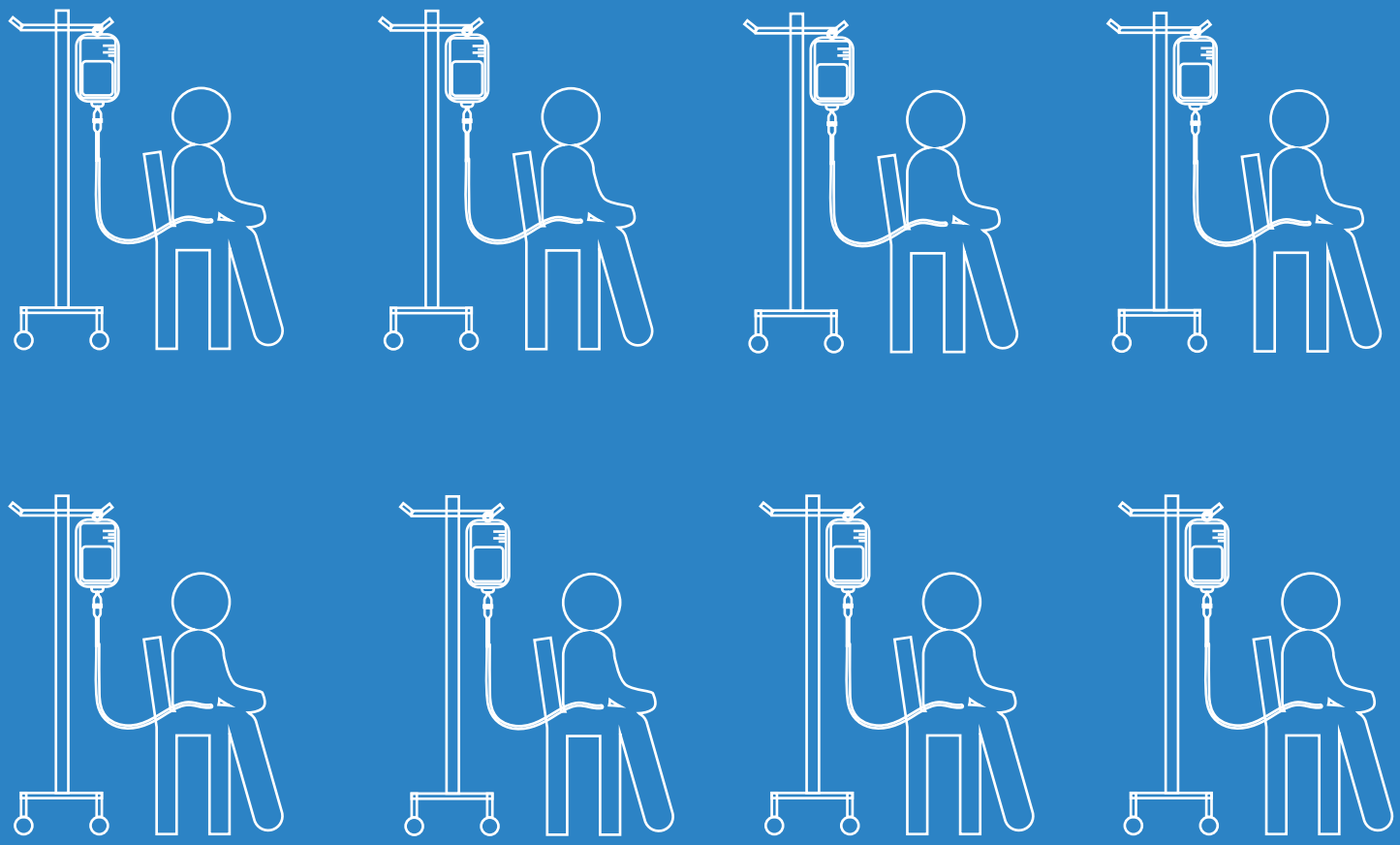
FINDING THE VALUE IN ARTIFICIAL INTELLIGENCE

Like many other industries, the life sciences sector has heard a lot of hype related to artificial intelligence (AI), blockchain, and other next-generation technology trends. Expectations are sky-high regarding the potential of these technologies to transform nearly every point along the healthcare continuum. And you can see that hope expressed in the strategic decisions made by power players as life sciences companies continue to invest in digital capabilities and resources. Various tech firms including IBM, Microsoft, and Google, as well as many smaller firms, are designing new tools for the healthcare sector; and regulatory agencies around the world are taking steps to incorporate these technologies into the regulatory process.

Advancements in artificial intelligence are also driving acquisition strategies in the industry as evidenced by Roche's acquisition of Flatiron Health in 2018. Flatiron Health's oncology-specific electronic health record (EHR) software represented a potential boon of impactful data for Roche to leverage in drug development.

Daniel O'Day, CEO Roche Pharmaceuticals on the acquisition, "This is an important step in our personalised healthcare strategy for Roche, as we believe that regulatory-grade real-world evidence is a key ingredient to accelerate the development of, and access to, new cancer treatments."

As organizations in the life sciences industry continue to explore, develop, and implement use cases for artificial intelligence, success will begin with the end in mind. Before collecting data or incorporating new data streams, organizations must carefully consider core business processes along with long-term strategy to best leverage artificial intelligence. When it comes to AI, more data doesn't always mean more insights – artificial intelligence can provide the answer, but only if we ask the right question. With a well-aligned strategy, a sustainable AI operating model will be based in foundations of strong data integrity, data management, and data governance.



PATIENT-CENTRICITY - SHOULD YOU BELIEVE THE HYPE?

Each year healthcare communications introduces a new set of buzzwords for the industry to rally around. For the past several years, that buzzword phrase has been “patient centricity.” Has the buzz been warranted? How effective has it really been? Are organizations really getting closer to the patient? What impact has it had?

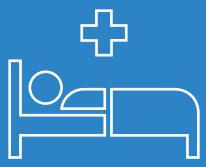
There is a strong precedent for life sciences organizations to adopt a more patient-centric approach. In the modern age, consumers have more choices and purchasing channels at their fingertips than ever before. Companies across various industries have chosen to adopt strategies that cater to a market-of-one, and now pharma and biotech organizations are no exception.

One way leading life sciences organizations are putting patients first is by communicating and demonstrating transparency. Patient-centric initiatives including education services, patient advocacy groups, and training programs provide value through communication and involvement and demonstrate a collaborative and value-focused mindset.

For example, in the fifteen years of drug development for Patisiran, RNAi powerhouse Alnylam Pharmaceuticals communicated early and often with both patients and physicians to understand the disease and develop a solution that provided value to patient needs. Alnylam’s patient access philosophy clearly states their investment in proactively providing value for stakeholders in patient care. This institutionalized patient-centricity isn’t just about making patients feel heard – study after study shows increased access to information leads to greater patient engagement and better results.

Moving into 2019, organizations can continue to improve patient-centricity by incorporating patient-advocate voices before bringing solutions to market. Despite advances in innovative medicines such as CAR-T therapies, genome-sequencing, and personalized medicine, major challenges remain around patients and their interactions with stakeholders in the healthcare ecosystem.

Before going after clinical outcomes, it is important for life sciences organizations to keep in mind:



HOW CAN A TREATMENT MAKE LIFE EASIER FOR PATIENTS?

HOW CAN A TREATMENT GIVE PATIENTS PEACE OF MIND?

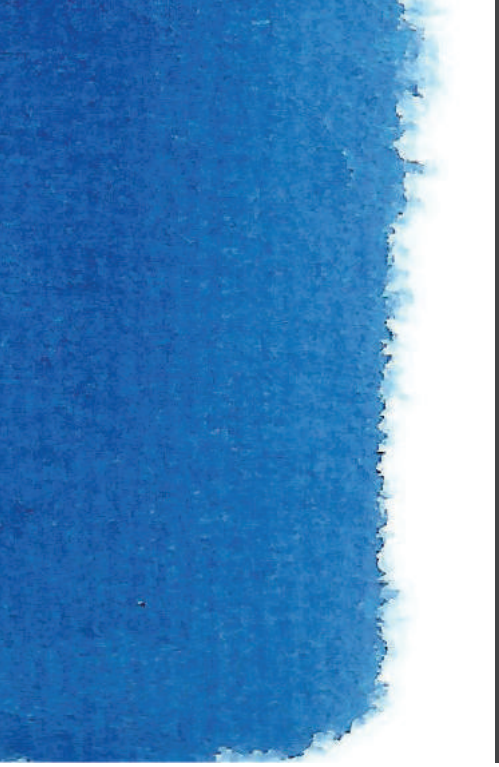
HOW CAN A TREATMENT BUILD TRUST WITH PATIENTS?

There also remains a need for greater diversity and inclusion of patients during the drug development stages all the way through disease management. True patient centricity reflects appreciation and understanding of all patients, their backgrounds, and unique characteristics. Involving patients early and often in the process not only leads to more pointed clinical solutions, but also builds trust and patient engagement - crucial components for improving pharmacovigilance and realizing better patient outcomes.

PATIENT-CENTRICITY AT WORK IN CLINICAL TRIALS

In efforts to become more patient-centric, organizations have been exploring options to create Decentralized Clinical Trials (DCTs), in which the treatment is better matched and tailored to the lifestyle of the patient. By incorporating digital tools and telemedicine solutions, organizations want to capture a more fluid and holistic view of patients' true experience living with the disease, as opposed to taking sporadic "snapshots" at specialized treatment centers. In this way, these "hybrid" trials, which are conducted partially at patients' homes through digital tools, offer a clearer picture of the efficacy of new therapies. The bottom line: greater insight into patients' lives can allow these organizations to design treatments that not only address the disease but align more seamlessly with patients' behaviors and habits.

Not only are DCTs a competitive advantage for organizations seeking higher patient enrollment and engagement, DCTs can potentially use fewer resources while producing higher quality data and more effective drugs. Within pharma and biotech circles, there has been plenty of discussion about how organizations can bring their drugs to market faster, and DCTs appear to be one of the leading strategies.



The tech giants have long been betting on this decentralized clinical trial trend to encroach into the healthcare space. In September 2018, Apple announced the Apple Watch 4's updated ability to capture an ECG signal, bolstering the company's strategy to become the digital touchpoint for patient data collection. Dozens of other tech companies, including Google, Fitbit, and Amazon, are adopting similar strategies.

The decentralized approach has also been widely supported by the FDA. For example, the Clinical Trial Transformation Initiative (CTTI) is a public-private partnership co-founded in 2007 by Duke University in partnership with the FDA to, among other goals, analyze the challenges of decentralization through telemedicine and mobile healthcare providers. In September 2018 at the DPharm conference in Boston, CTTI released new recommendations for organizations to overcome the legal, regulatory, and practical hurdles for planning and conducting DCTs.

LOOKING FORWARD TO M&A IN 2019

2018 was the year many predicted mergers and acquisitions would increase across the life sciences space. While such activity didn't reach expected levels, the same factors that made so many bullish on M&A in 2018 are still reflected across the industry moving forward into 2019. Constantly building margin pressures and predictions of a near-term recession in the U.S. have also driven the unloading of non-core assets in big pharma over recent years, a trend that's expected to continue into 2019 and drive more targeted, bolt-on activity in the M&A space.

While regulatory uncertainty represents a key risk to successful M&A activity, it remains one of the most effective growth strategies for the industry. Just in the first week of 2019, Bristol-Myers Squibb Co. announced it's intent to buy Celgene in a deal valuing the cancer drug specialist at $74 billion. Analysts are divided on how many mega deals like this we can expect in 2019 as historical post-deal failures have given some industry leaders pause.

The primary M&A challenge is to successfully integrate disparate processes, systems and cultures to achieve the desired business outcomes. For example, from a supply chain perspective, an ongoing challenge is to integrate distinct supply chains, best address the potential redundancy in the combined supply and distribution network, make the next-generation investment decisions that best support the business strategy, and maximize overall efficiency. This requires a comprehensive data-driven network footprint analysis of multiple scenarios that takes into account strategic considerations, capital investments, service levels, R&D capabilities and total costs to create truly integrated and efficient supply chains that are agile, responsive, and resilient. With increased M&A transactions predicted in 2019, supply chain rationalization continues to be a strategic lever that creates value and improves bottom line for drug makers.

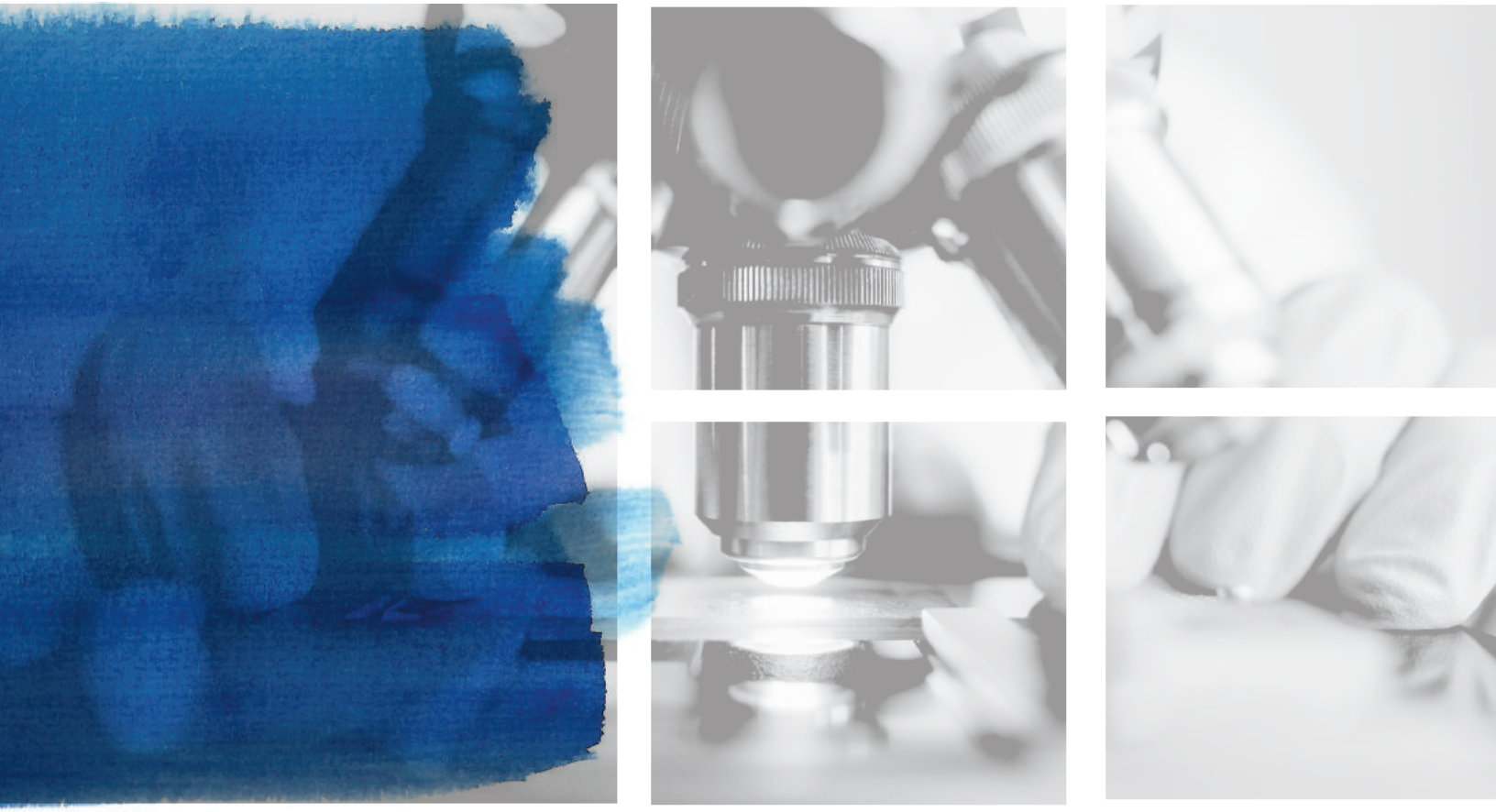
Whether it's supply chain operations, enterprise technologies, or front or back office functions, integration challenges abound in the life sciences space. As life sciences companies increasingly look to acquire outside-industry targets, the integration challenge can prove even more disruptive. Moving forward through 2019, leaders in the life sciences industry should approach due diligence with a renewed focus, incorporating partners with industry and functional expertise throughout the lifecycle of a deal to best identify and mitigate the most impactful integration pain points.

OPTIMIZING CLINICAL OPERATIONS

Since the end of the blockbuster drug era at the turn of the century, drug manufacturers have experienced decreased rate of success while facing rising R&D costs. In fact, industry analysts have predicted a potential 0% average ROI on R&D in the near future. This imbalance in clinical development represents a significant risk to future development, profitability, and growth in the industry. In 2019, industry leaders must reassess current clinical models to drive new capabilities, processes, and strategies to improve outcomes and gain efficiencies. It's not just cost driving improvements to clinical operations – as drug development becomes increasingly complex and individualized, a more flexible and dynamic clinical operations model is necessary to keep pace with therapeutic innovations.

One promising area of focus in clinical operations for life sciences companies in 2019 will be optimizing the clinical supply chain. Reigning in clinical supply chain costs drives greater need for improving forecast accuracy, right-sizing drug supply, maximizing internal and external integrations as well as enabling real-time visibility and control. Furthermore, as speed to market becomes even more critical in 2019, companies have started to take a more proactive approach to designing and building an effective and efficient supply chain in preparation for commercialization.

Throughout 2019, more companies are projected to embark on a journey to transform their clinical supply chains to be leaner, more reliable and responsive and, most importantly, of strategic significance. While historically R&D has had limited adoption of operational excellence principles, more organizations will likely start to embrace lean principles along with leading practices from their commercial counterparts to optimize their clinical supply chains and deliver on the vision of "the right dose of the right medicine delivered to the right patient at the right time…and at the right cost".



CLOSE

2019 promises the life sciences industry another year of disruption, innovation, and new challenges. Navigating successfully through the year will require a flexible mindset willing to shed long-held beliefs about traditional business models, processes, and systems. It's more critical than ever to look deeply at core strategies and operations to assess their role in creating value for the patient. As regulators, legislators, payers, and patients continue to focus a microscopic lens on the life sciences sector, industry leaders must respond with transparent, data-driven strategies to effectively demonstrate and communicate value.

ABOUT JANEL FIRESTEIN

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