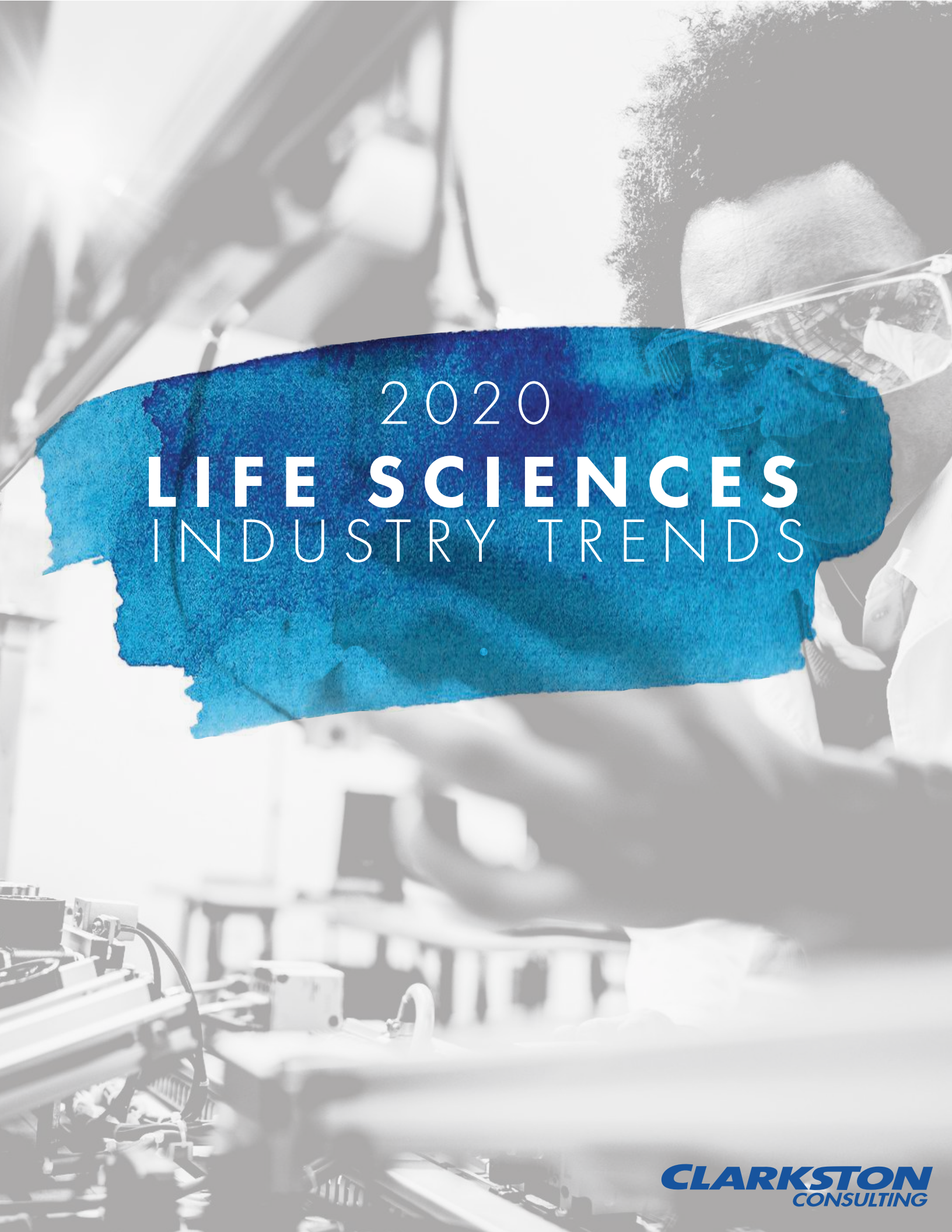


2020 LIFE SCIENCES INDUSTRY TRENDS

CLARKSTON CONSULTING

Characterized by complexities and breakthroughs, the life sciences industry finds its momentum in the innovation of novel therapies and operational excellence. Despite pressure from vociferous stakeholders and scrutinizing legislative bodies, 2019 saw exponential growth in treatment capabilities and health management avenues across the board.

Challenges remain as 2020 brings heavier regulatory and commercial pressures. Debates over opiates, drug pricing, and expensive immunotherapies make it imperative for leaders to reconcile market success with patient-centricity, while portfolio diversification requires strategic planning through patents and supply chain challenges. In navigating these obstacles, digital solutions and novel breakthroughs can allow companies to recoup customer trust, embrace efficient supply chains, and enjoy cost-effective paths to market.

Here, we explore these and other trends in depth as they work to shape the life sciences industry in 2020. Leveraging extensive industry expertise, we aim to highlight the areas where leaders can harness opportunities as the year unfolds.

ADMINISTRATIVE EYES CONTINUE TO SCRUTINIZE DRUG PRICES

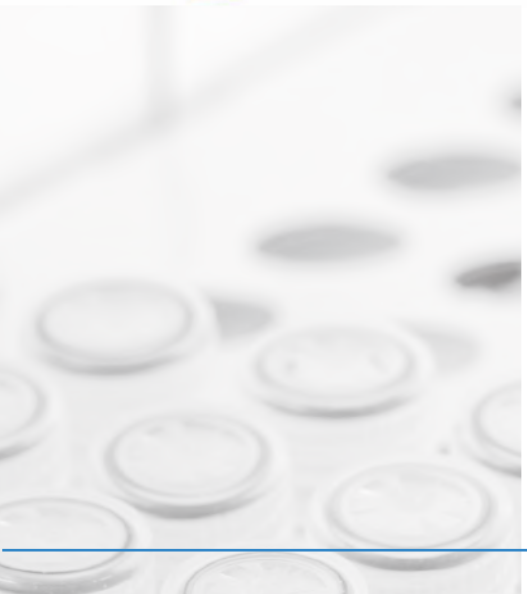
Numerous federal policy proposals cast a cloud over the industry in 2019, and while few are credible threats, each added kindling to ever-fervent drug pricing debates. In April 2019, the state of Colorado enacted **HB 19-1131,** which requires companies to share the "sticker" prices of marketed drugs with prescribing doctors in an effort to improve the patient-provider relationship. The SPIKE Act **(H.R. 2069)** and the FAIR Drug Pricing Act **(S.1391),** proposed in spring 2019, stipulate that drug companies should not only notify congressional bodies of impending price increases, but also submit documentation to justify increases over a certain threshold.

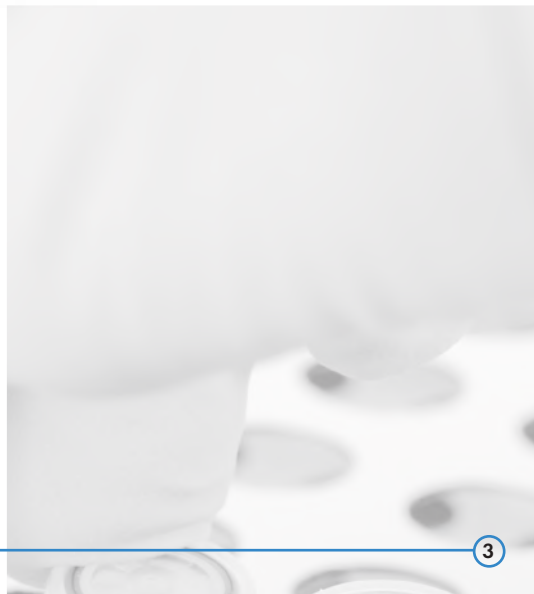
Looking forward, drug pricing remains a bipartisan issue for the 2020 presidential candidates. Republican candidate President Trump supported a plan this year to **import Canadian drugs** for U.S. citizens at a lower price point. On the Democratic side, Sen. Warren, former Vice President Biden, Sen. Harris, and Pete Buttigieg have each voiced support of drug price negotiation for government programs, while Bernie Sanders is in strong favor of Trump's importation efforts.

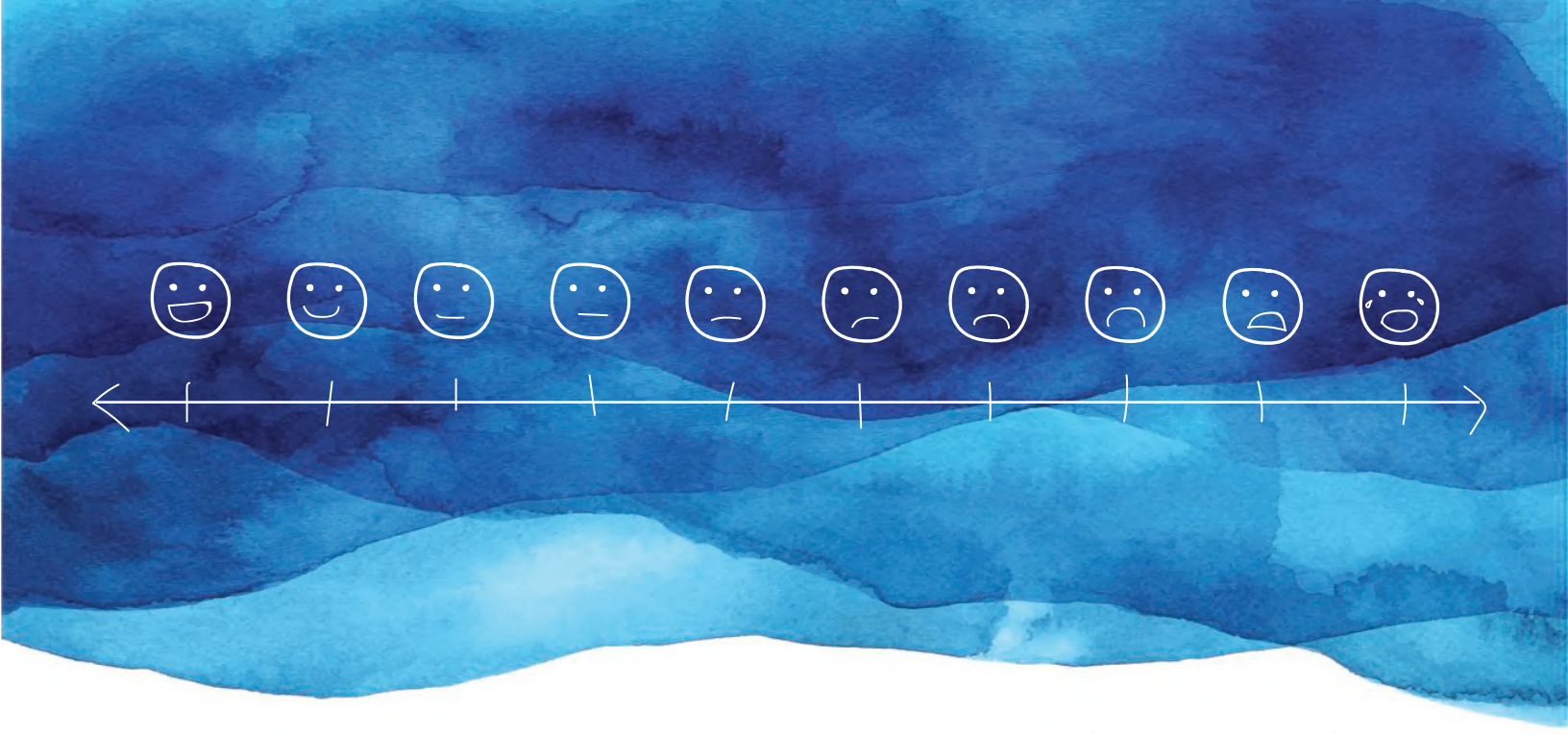
Most imminently, in September 2019, House Speaker Nancy Pelosi introduced a **draft plan** that would allow the Secretary of Health and Human Services to negotiate price points with drug companies and apply these prices to both Medicare/Medicaid and the private market, as well as enforce stiff profit penalties for companies that refuse to negotiate. Despite the ferocity of this potential legislation, the system will remain flexible so innovative and novel therapies can protect premium price points.

PRICING METHODS FOR EXPENSIVE CELL AND GENE THERAPIES

But the debate around pricing extends further, going beyond traditional drugs to cover increasingly expensive cell and gene therapies. Payment options for these therapies are undergoing a paradigm shift, as the current pricing structure poses issues for nearly every stakeholder. Currently, high price points disincentivize insurers from covering such therapies as debates over lifetime savings and treatment efficacy drive a disconnect between patients and treatments. As this sparks discussion over outcomes-based arrangements, immunotherapy leaders can explore **novel pricing structures** such as crowdfunding, pay-over-time, and subscription models to bridge the gap between their treatments and the patients they serve.







REPAIRING THE ROAD TO CHRONIC PAIN MANAGEMENT

2019 saw landmark rulings in the global opioid crisis, highlighting medication abuse as the central issue—and that the need for pain management is more pressing than ever. **Johnson & Johnson** had to shell out millions after a ruling in August, and in September **Purdue Pharma** filed for Chapter 11 bankruptcy as the company settled thousands of lawsuits. It's unclear whether justice-oriented headlines will stagnate; however, the industry begins turning to novel and innovative ways to manage pain to both mitigate abuse and address chronic need.

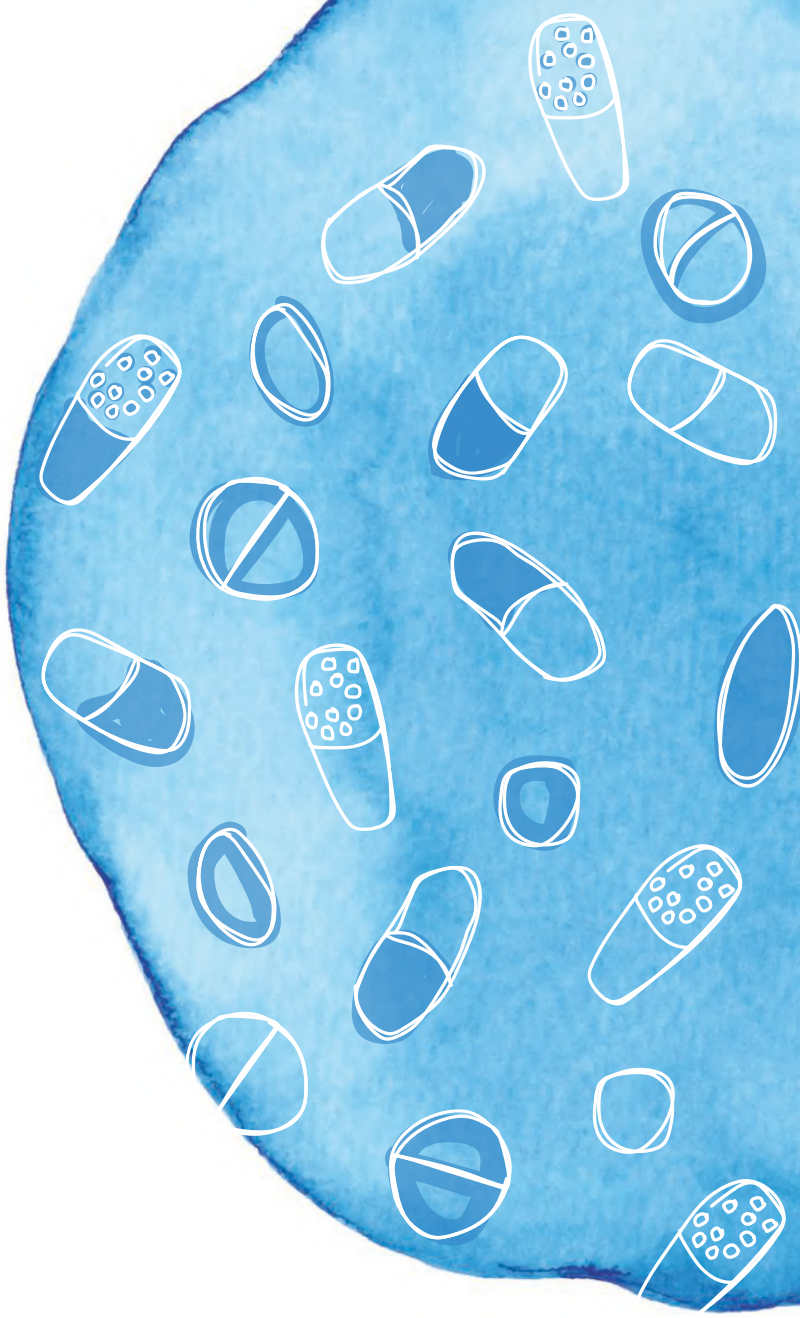
$40B

The global medicinal cannabinoid market is projected to exceed $40B by 2024,

SOURCE

Addiction treatments are on the rise, and medical marijuana continues to strengthen its foothold as an alternative pain treatment. The global medicinal cannabinoid market is projected to **exceed $40B by 2024,** posing a massive new treatment arm for varying medical conditions, even going beyond pain management. There are, however, vast impacts on regulatory and payer systems as cannabis and its by-products remain federally regulated as DEA Class I drugs. As federal legalization efforts slowed over 2019, state-specific and global initiatives remain the key to this market's continued expansion.

GENERICS & BIOSIMILARS DEMAND SURGES



Despite high price points, increasing competition across immunotherapies continues to provide more options for payers, while traditional generics continue as pillars of a diverse product portfolio. In November 2019, **Sandoz won approval for a generic of Amgen's Neulasta,** making this the third Neulasta biosimilar approved to treat infection in cancer patients undergoing chemotherapy. Shortly after, **Biogen announced a partnership** with a Korean developer for biosimilars of the eye disease drugs Lucentis and Eylea.

Within the biosimilar realm, however, **patent thickets** continue to slow startup activity and diversification. Outside the patent thicket, advanced therapies have increased clinical trial activity by 67% in the last four years. This surge in demand has created increased utilization of spaces and the use of CMOs, long facility waitlists, and even pre-contracting for spaces still under construction. However, despite this **manufacturing bottleneck,** advanced therapies and personalized medicines march onward with massive success.

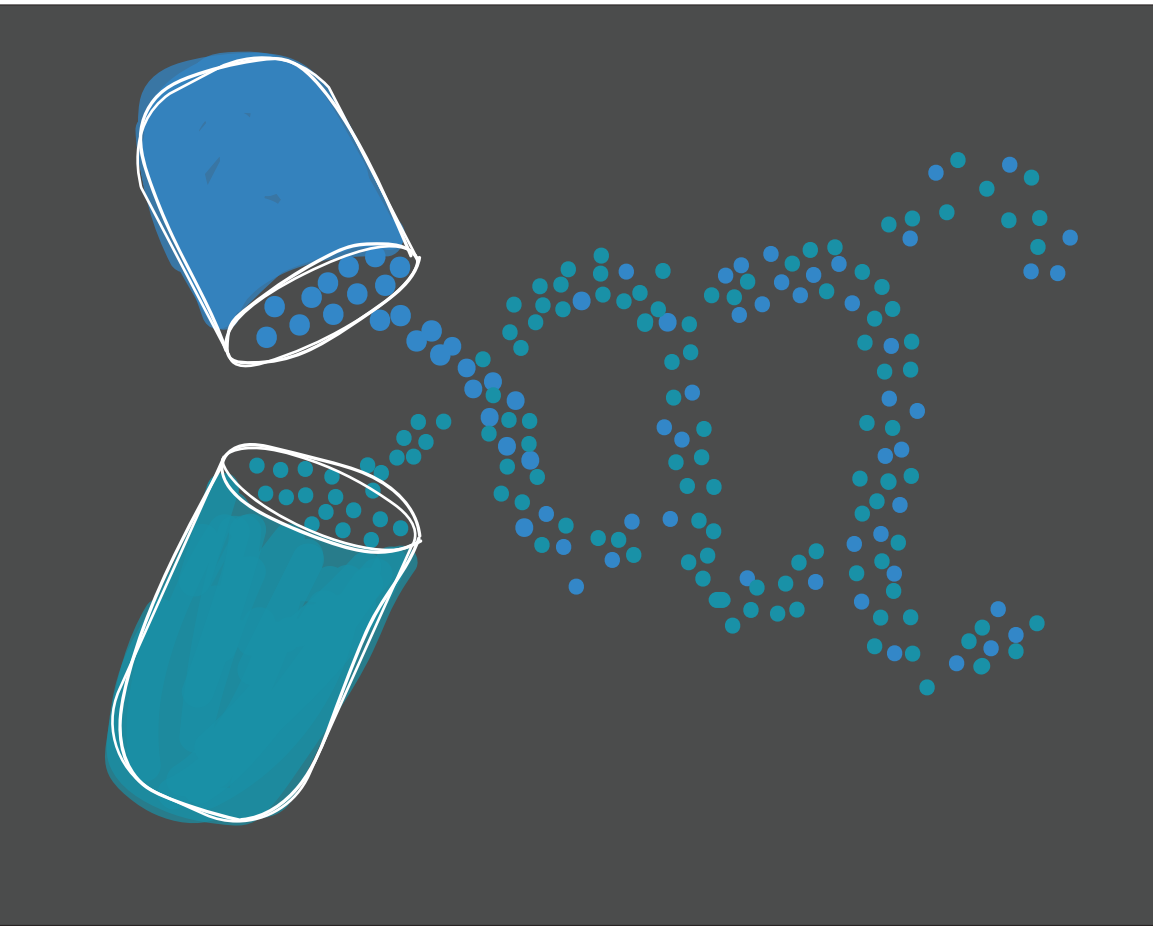
IMMUNOTHERAPIES CONTINUE WITH NOVEL BREAKTHROUGHS

Immunotherapies continue to show promising results in varying disease categories, but cancer treatments in particular are accelerating quickly. For instance, Nektar Therapeutics' found success with an immunotherapy to boost the efficacy of Bristol-Meyers Squibb's cancer drug Opdivo. An ongoing, early-stage **trial for pancreatic cancer** is attempting to test the efficacy of varying drugs against a patient's own cancer cells by treating them in vitro.

Off-the-shelf cell therapies, specifically CAR-T, remain in high demand. In December 2019, Celgene, Bluebird, and J&J presented promising **trial data for CAR-T in blood cancer** at the American Society for Hematology's annual meeting. With the high number of ongoing and imminent trials, numerous avenues for growth and new market entry remain open.

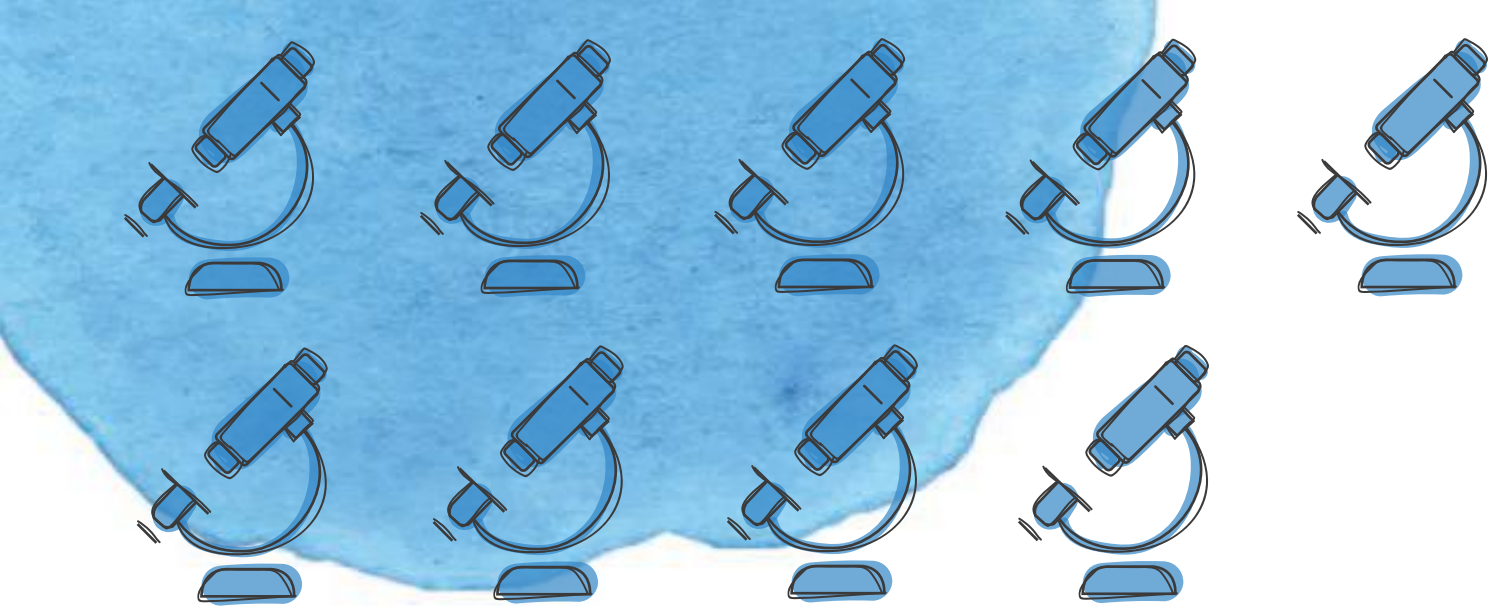
INNOVATIONS IN THE PERSONALIZED MEDICINE SUPPLY CHAIN

Personalized medicine marks the shift away from a demand-driven model to a patient-driven model. Because of its highly specific nature, the very existence of individualized medicine implies data. Here, 2019 saw numerous tech companies stepping into the healthcare realm, forming contracts that will see fruition in 2020. Internet-of-things (IoT) tracking sensors in the **personalized medicine supply chain** have vastly improved the reliability and accuracy of cold-chain transport, while flexible manufacturing has enabled cost-effective production of small, dynamic medicinal batches. **While challenges remain,** the right mix of contracting, coordinating, and tech enablement can efficiently match production with demand.



GENETIC TESTING WILL REQUIRE NEW GOVERNANCE

Biomarker testing and research remains a source of debate, despite their potential to revolutionize medicinal treatment and diagnostic processes. The FDA initially sparked the debate in August 2019 with a **warning against sharing genetic test results with patients,** for fear this could endanger patients by encouraging them to start or stop medication or seek treatments without the approval of their preferred provider. Nevertheless, genetic testing remains promising, but good data governance and patient relationship management remain key to the industry's success.



DIGITAL DOORS FOR CLINICAL TRIAL INNOVATION & TREATMENTS

While mobile integration and network coverage made **decentralized clinical trials** possible, blockchain and traceability continue to make clinical trials adaptable to patients' lives and conditions. **Innovative trial designs** can embody patient-centricity while remaining flexible by using real world data and advanced digital management technologies. The FDA continues to support such digital solutions, including **prescription digital therapeutics,** which harness software in the treatment of mental health outcomes, insomnia, and even neuromuscular conditions like multiple sclerosis. Digital solutions take time, require digital data capture and harmonization, and often require expert IT integration. However, they remain highly cost-effective and capable of vastly increasing speed to market.

ARTIFICIAL INTELLIGENCE CATALYZES R+D AND DIAGNOSTICS

In October 2019, a machine learning model searched aggregate medical data on 1.7 million Americans and flagged 1.3 million of them as likely inheritors of familial hypercholesterolemia, a chronic condition for which 90% of sufferers in the U.S. go undiagnosed. The study, **published in *The Lancet,*** was the first of its kind, and while it's unclear how many of the flagged individuals actually have the condition in question, AI's diagnostic capabilities remain unparalleled. A predecessor to this study is programmer **Matt Might,** who created an experimental AI that was successful in diagnosing a rare infection in his son, who suffers multiple chronic conditions.

Sensing the opportunity for AI in both diagnostics and R+D, Novartis and Microsoft recently inked a **5-year AI alliance** within which the companies plan to develop applications for Microsoft's artificial intelligence capabilities throughout Novartis' drug development. Google, Facebook, and Amazon are also investigating **using AI to identify the structure of proteins** involved in diseases. As data availability and capabilities rise, the need for good data governance becomes more important than ever. As with any new endeavor, leaders should look for long-term, holistic applications and formulate a detailed strategy to harness the benefits of such technologies.

CLOSE

Forward-thinking strategies will be crucial to success in 2020 as creating value for the patient remains a fundamental building block for longevity. As digital solutions unlock new methodologies, a flexible mindset can enable leaders to fully realize the opportunities ahead. With a multitude of avenues for growth, it's imperative to take a critical look at core capabilities and assess their role in strategy. As payers, patients, and regulators become increasingly wary of the industry's core values, leaders must demonstrate the value that data governance, research, and commercialization bring to the patient. Effectively demonstrating strong data practices, clinical efficacy, and forward-thinking strategy remain crucial to communicating value and delivering patient outcomes.

ABOUT CLARKSTON CONSULTING

Businesses across life sciences industries partner with Clarkston Consulting to enhance strategic decision-making, improve operational efficiencies, implement new technologies, and promote business growth and market diversification. Leveraging deep functional and industry expertise, our people discover, design, and deliver solutions that fit your business, your goals, and your future. At Clarkston, your purpose is our purpose.

For more information about how we can help your company with the challenges and opportunities in life sciences, please contact us.

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