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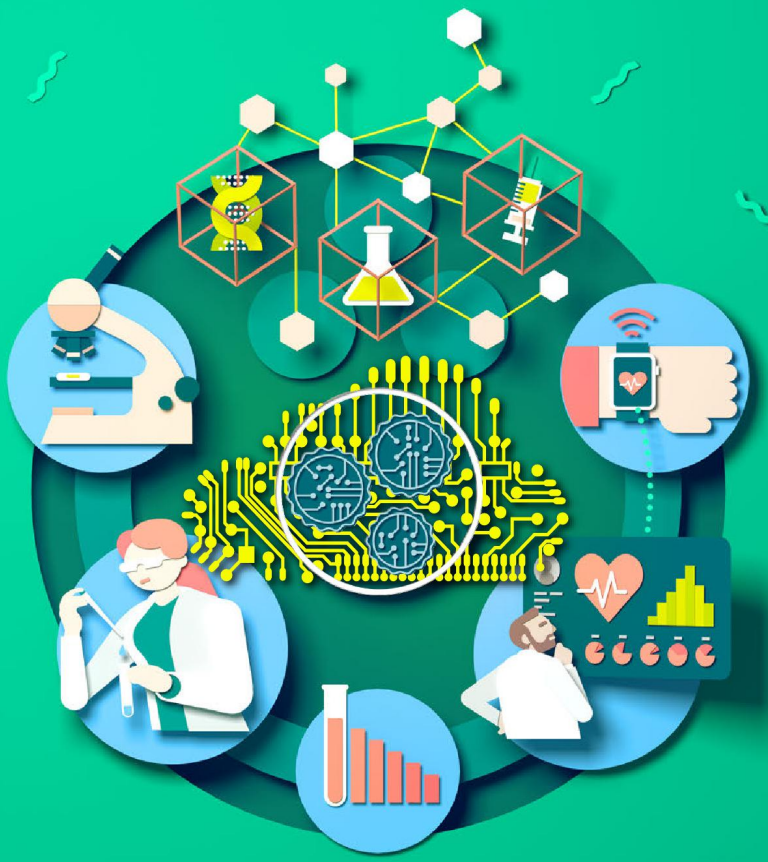

2020 global life sciences outlook

Creating new value, building blocks for the future

About the author

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Introduction

THE LIFE SCIENCES sector is at an inflection point. The promise of cell and gene therapies is being delivered to patients; rare diseases, previously believed to be incurable, are on the precipice of real cures.[1] Artificial intelligence (AI) and machine learning approaches are raising expectations that therapy discovery and development may not only be more innovative, but also more time- and cost-effective. Data-driven approaches have the potential to create value across manufacturing, the supply chain, and the entire health care ecosystem.

As technology and behavioral science converge, the focus is increasingly shifting to disease prevention.[2] Consumer wearables now have medical-grade sensors,[3] and telemedicine, remote monitoring, and virtual trials are reducing complexity for patients.[4] Medical algorithms and connected devices are delivering data everywhere.[5]

In 2020, biopharma and medtech organizations will be looking for new ways to create value and new metrics to make sense of all the data. As patient-centric models have been adopted within the industry, they are now informing operational approaches and setting the foundation of personalized health care.[6] The human experiences—of patients, the workforce, and ecosystem partners—are interrelated and affect business outcomes. With the goal of creating value for all stakeholders, organizations can aspire to find real value for themselves and their shareholders in the coming year.

Creating new value

TO PREPARE FOR the future and remain relevant in the ever-evolving business landscape, biopharma and medtech companies need to discover sources of significant new value creation. As data-driven technologies provide organizations with treasure troves of information, and automation assumes mundane tasks, new talent models are emerging for the future of work based on purpose and meaning. Cultivating human strengths—for probing data, curating information, and asking the right questions—can help humans work with technology to think exponentially.

Is it time for the next generation of key performance indicators (KPIs)? What are biopharma and medtech companies measuring now, and what could they be measuring in 2020 to find meaningful insights, improve the human experience, and create more value? The answer may well lie in strategizing on the basis of *metrics that matter*.[7]

HUMAN VALUE OF A TECHNOLOGY ACQUISITION: FLATIRON HEALTH'S ARMY OF MEDICAL CURATORS

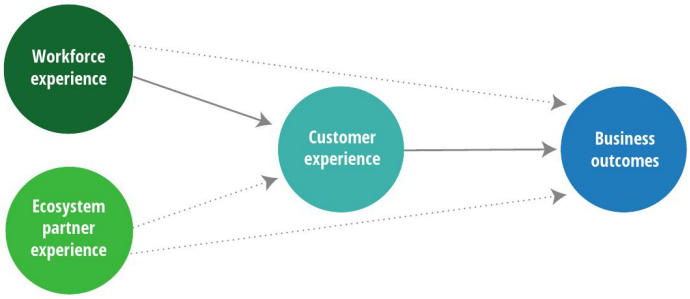
In cancer treatment and research, experts say the majority of value is in unstructured data, the free text fields of pathology reports and clinical notes.[8] Today, while technology can "read" these fields, extracting the most useful nuggets still requires humans.[9]

To tackle this hard problem, Flatiron Health realized they needed more than technology. They hired an army of trained medical professionals to painstakingly curate large streams of unstructured data and train its machine learning–models. By normalizing both unstructured and structured data from electronic health records (EHRs), Flatiron Health made them more useful for clinicians and researchers.[10] By accelerating cancer research,[11] the startup created new value—with humans and technology—and was acquired by Roche for US$1.9 billion in 2018.[12]

"It would be wonderful if we could have a common framework that applies across customer, partner, and workforce. If there is a common way to think about 'experience' across all three parts of the ecosystem, this could drive an enterprise's competitive advantage."[13]

FIGURE 1

Connections between stakeholder (human) experiences and business outcomes



Source: Art Mazor et al., *Measuring human relationships and experiences: Blurring lines and shifting sands,* Deloitte Insights, June 20, 2019; Deloitte analysis.

MEASURING THE HUMAN EXPERIENCE

Biopharma and medtech organizations could benefit by implementing a holistic strategy to measure the human experience for all stakeholders (figure 1).[14] While advances in technology appear to drive more efficiency, leaders should more deeply consider ways to increase value and meaning across the board—for workers, customers (patients), and ecosystem partners (vendors, alliances, advocacy groups). Successful organizations are not just tracking satisfaction but mapping touchpoints and determining the ease of interactions in the ecosystem.[15]

Executives in marketing, human resources (HR), operations, and information technology (IT) should be looking for opportunities to break down silos and collaborate. Working together, they could create and track a common set of experience measures for workers, customers/patients, and ecosystem partners that will lead to better business outcomes.[16]

Creating value for patients, care partners, and care teams

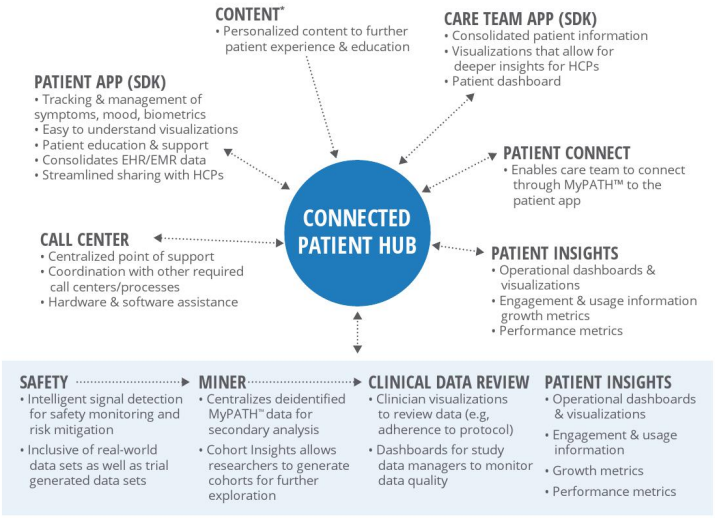
FOCUS ON A HOLISTIC PATIENT EXPERIENCE

A holistic patient experience is about understanding the experience of a patient living with a specific disease or condition. By mapping all the touchpoints that patients may experience throughout their journey and with their care teams, an empathic solution could be built to address their needs—from diagnosis to maintenance. Providing a holistic patient experience could reduce complexity for patients and caregivers. One way to manage that experience and create value through technology could be a patient hub (figure 2) that digitally connects patients and their caregivers.

FIGURE 2

The ConvergeHEALTH MyPATH Platform

The holistic patient experience is driven by an integrated set of solution components



* Content management system can be housed internally or externally.

Source: ConvergeHEALTH MyPATH, Deloitte, 2019.

A holistic patient experience could not only help patients manage their disease, but also improve adherence and outcomes. For example, medication adherence tools can help identify gaps in care, and intelligent safety monitoring can predict adverse events through wearables and provide early intervention. Research can be elevated by rich and comprehensive patient data and a learning health care system where clinical trials are designed around real-world patients.

DEEPER UNDERSTANDING OF CONSUMER NEEDS

Medtech companies should have a deeper understanding of the end user. By creating scenarios that demonstrate how new and existing devices and services could improve patient outcomes, they may also create value for key health care stakeholders.[17]

A better understanding of consumer needs could lead to the development of more user-friendly devices that could be sold directly to the consumer. In a new category of products—the self-fitting air conduction hearing aid—Bose offers a device that does not need the assistance of a hearing care professional. No preprogramming or hearing test is necessary. To create value, medtech companies should also explore ways to offer patient-centered services in nonclinical settings.[18]

Creating value through more inclusive clinical trials

For decades, clinical trials have helped researchers discover solutions and treatments for diseases and avenues for further study, but have they been inclusive enough? Some experts say no, and the consequences of excluding representative populations may be profound.[19] In order to better understand the drugs and procedures that will effectively treat disease, there is a growing mandate to increase participation with members of demographic groups who will eventually receive these treatments.[20]

HELA AND THE POPULATION SKEW IN CLINICAL TRIALS

Research would not be what it is today without the "immortal cells" taken from an African American woman, named Henrietta Lacks, who died in 1951 with an aggressive form of cervical cancer. HeLa cells, named after her, have allowed scientists to make breakthroughs in the diagnosis, treatment, and prevention of cancer, polio, HIV, HPV, and many other diseases. No other human sample matches the HeLa cell line in ubiquity or notoriety. More than 75,000 mentions can be found in *PubMed* papers. The cell line is still used in medical research today.[21]

Unfortunately, Henrietta Lacks' cells were taken without her permission.[22] For minorities, mistrust of the medical community could be a barrier for clinical trial participation based on past injustices, like medical experimentation.[23] Nearly 40 percent of Americans belong to an ethnic or racial minority, but participants in clinical trials may skew between 80 to 90 percent white.[24]

INCREASING PARTICIPATION IN CLINICAL TRIALS

To have statistical value, it is critical that clinical trials are representative of patients who will eventually use a drug or therapy. A major challenge for the biopharma segment is recruiting trial participants from important demographic groups, including racial and ethnic minorities, women, and the elderly.[25] A review of 50 years of clinical trials, funded by the US National Institutes of Health (NIH), found that in two-thirds of trials, the average age of study participants was younger than the actual averages for patients with the diseases being studied.[26]

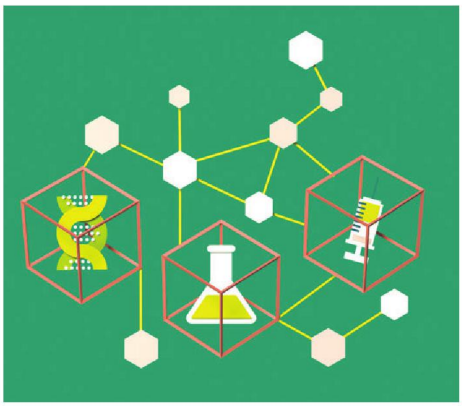
Research shows that making trial participation available to patients is vital,[27] and underenrollment of critical groups reduces the generalizability of research findings.[28]

Resolving disparities becomes particularly important as cancer treatments continue to move toward precision medicine.[29] Fewer than one in 20 adult cancer patients enroll in cancer clinical trials.[30] Those over 65 years of age are often omitted from these trials but make up the lion's share of patients for health conditions such as cancer, cardiovascular disease, arthritis, Parkinson's, and Alzheimer's.[31]

Another challenge for including vulnerable populations, like the elderly, is likely patient safety. Having an elderly patient on a study could put it at risk for more severe adverse events and possibly more protocol deviations (due to comorbidities, impaired social support, and cognitive and functional impairment).[32] Partnering with patient advocacy groups could help life sciences companies better design trials that may meet the needs and safety concerns of older adults.[33]

IMPROVING ACCESS TO TRIALS

In a 2019 survey, more than 75 percent of patients cited structural and clinical barriers as the reasons for not participating in trials.[34] Structural barriers include access to a clinic and absence of an available trial. Clinical barriers include patients not being eligible due to narrow eligibility criteria, even if a trial is available, and the presence of comorbid conditions.[35]



For those not living close to places with clinical trial facilities, telemedicine may provide one option. Through virtual clinical trials, any qualifying patient who wants to participate in clinical research could become a part of ground-breaking research.[36]

In the future, partnerships with patient advocacy groups, physician groups, and medical associations could improve communication and increase patient and provider education about the benefits of virtual clinical trials. Like telemedicine, greater adoption of new technologies and AI could also increase access to medical research and expand diversity.[37]

However, even with inclusion, there may be differences in trial benefits. Recent research shows that low-income cancer patients and those without insurance may not experience the same benefits that other cancer patients do. Researchers concluded that trial sponsors may need to think about how cancer trials are designed, so that they account for these differences for this important patient group.[38]

GOVERNMENT AGENCIES' EFFORTS FOR MORE INCLUSIVE TRIALS

Government agencies have made a few efforts to make clinical trials more inclusive. In 2019, the US National Institute on Aging (NIA) launched a toolkit for older adults and their caregivers, including underrepresented populations, to encourage research participation.[39] The Recruiting Older Adults into Research (ROAR) toolkit is available in English, Spanish, and Chinese, and includes a tip sheet that addresses:

- What a clinical trial is
- Where to find a clinical trial
- What happens in a clinical trial
- Why it is important for everyone to be included in trials
- Benefits and risks
- Safety and privacy
- Definitions of unfamiliar terms[40]

In 2020, the US Food and Drug Administration (FDA) will continue to pay close attention to age diversity in clinical trials.[41] The NIH's "All of Us" precision medicine initiative has had some success—with 80 percent of participants representing communities that are historically underrepresented in research.[42] The Center for Drug Evaluation and Research (CDER) Drug Trials Snapshots are showing a positive trend in trial demographics. For example, female inclusion increased from 40 percent in 2015 to 56 percent in 2018, and African American participation doubled from 2015 to 2018 but is still low at 10 percent.[43]

Creating new value through meaningful work

Creating value and meaning are likely to become more important in the future of work.[44] Some even say that we are moving toward a passion economy—where meaningful and value-based work is an important factor in accepting a job.[45]

NOT JUST TALK ABOUT PURPOSE, BUT MEANINGFUL ACTION

Deloitte's most recent and largest millennial survey of 16,425 respondents from around the world found that the next generation of talent wants to see businesses take meaningful action and not just talk about purpose. Millennials (born 1983–1994) and Gen Zers (born 1995–2002) were found to show deeper loyalty to employers who boldly tackle the issues that resonate with them most, such as protecting the environment and unemployment.[46]

President of Novartis Pharmaceuticals, Marie-France Tschudin, says that she is being reverse-mentored[47] by millennials in her company in order to gain a better understanding of this generation's needs in the workforce. Tschudin says that to win in this era of massive change, Novartis' focus is on its people and a flexible, agile culture, despite being a company of more than 100,000 employees. Novartis' talent principles are based on being "curious, inspired and unbossed."[48]

Biopharma and medtech organizations should look at emerging technologies, meaningful work, and flexible work models to lure this next generation of talent that has the potential to create more value, not just for themselves, but for customers, other stakeholders, and ultimately, the organization as well.[49]

THE FUTURE OF MANAGEMENT: A DEEPER SENSE OF PURPOSE

The evolutionary breakthroughs of human collaboration are defined along a spectrum of colors, according to Frederic Laloux, author of *Reinventing Organizations*. He identifies pioneering organizations—large and small, for-profit and not-for-profit—as those that are moving toward self-management, wholeness, and a deeper sense of purpose. These "teal" organizations are seen as living entities, oriented toward realizing their potential.[50]

Self-management. Organizations based on peer relationships, not hierarchies. People have high autonomy in their domain and are accountable for coordinating with others. Power and control are distributed across the organization.[51]

Wholeness. Organizations that provide an environment where people are free to express themselves and reclaim their inner wholeness. This brings unprecedented levels of energy, passion, and creativity to work.[52]

Evolutionary purpose. Organizations with agile practices that sense and respond, replacing the machinery of plans, budgets, targets, and incentives. Paradoxically, Laloux says that by focusing less on the bottom line and shareholder value, these organizations generate financial results that outpace those of competitors.[53]

One example of a teal organization is Heiligenfeld, a 600-employee mental health hospital system based in Germany, which applies a holistic approach to patient care. Inner work is woven deeply into daily life at Heiligenfeld. Every week, colleagues from five hospitals come together for 75 minutes of reflective dialogue around a theme, such as dealing with risks or learning from mistakes.[54]

FOCUS ON CAPABILITIES, NOT JUST SKILLS

In the workplace, when conditions, tools, and requirements change rapidly, organizations, systems, and practices should assimilate. Over the last few years, the focus has been on reskilling, but growing in importance will be the enduring human capabilities that allow individuals to learn, apply, and effectively adapt.[55]

In order to be successful, leaders should look at how jobs can be redesigned, and work reimagined, around human-machine collaboration, in ways that enhance workers' capabilities and augment human abilities. A work culture built around capabilities and diverse workgroups could have a positive effect on customer experience and business outcomes (figure 3).[56]

Creating value in the market, tracking discernible change

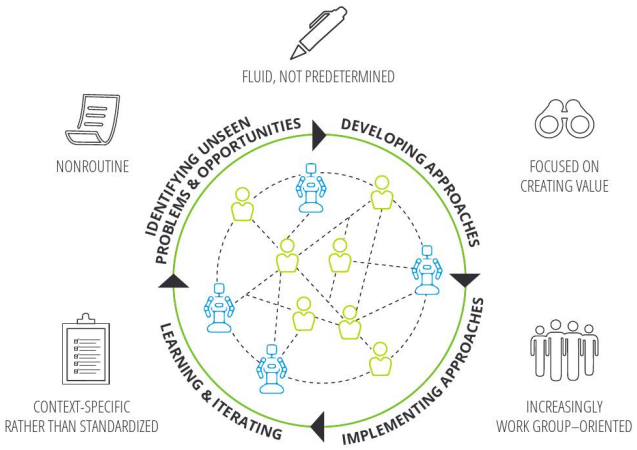
PORTFOLIO TRENDS: BILLION-DOLLAR DEALS AND VALUATIONS

Life sciences deal values rise, number of deals down

Compared with a robust first half for 2019, the third quarter showed signs of a significant slowdown for life sciences mergers and acquisitions (M&A).[57] With a rocky market, trade deals in flux, and talks of recession in many parts of the world, companies may be waiting for valuations to fall even lower before they move forward with a transaction.[58]

FIGURE 3

A new vision of human work oriented around creating new value



Source: John Hagel, John Seely Brown, and Maggie Wooll, *Skills change, but capabilities endure*, Deloitte Insights, August 30, 2019.

While the number of deals for the year may be trending downward, the value of the deals is considerably higher for the first three quarters of 2019—US$181.7 billion compared with US$135 billion in deal value at the same time in 2018.[59] Through Q3 2019, companies from the United States were acquirers in 537 deals and targets in 480 (figure 4). Chinese companies were acquirers in 411 deals and targets in 382.[60]

On the heels of the completion of the US$74 billion acquisition of Celgene by Bristol-Myers Squibb,[61] one of the largest M&A deals announced in 2019 was for a gene therapy company. In late December 2019, Roche completed its US$4.4 billion deal to acquire Spark Therapeutics following the receipt of regulatory approval from all government authorities required by the merger agreement. Spark becomes a wholly owned subsidiary of the Roche Group.[62]

In 2020, large pharma companies will likely need to keep acquiring and making bets on cell and gene therapy companies, focused on oncology and rare diseases. However, significant work remains to be done in scaling the gene and cell therapy model, from development through commercialization, which in turn, is putting pressure on legacy models.

In the future, smaller companies may ultimately take an increasing share of the market from big pharma by developing and commercializing products independently. With the recent influx of private equity and venture capital (VC) investment going into the biotech market, emerging companies have been able to pursue development into later stages. In the long run, this may make it more difficult for big pharma to buy innovation.[63]

Biotech exits and initial public offerings (IPOs)

As of October 2019, there were 61 biotech IPOs, 127 biotech companies acquired, and 124 biotech companies ceased to exist worldwide.

FIGURE 4

China on the heels of the United States in the number of global life sciences mergers and acquisitions among 10 leading countries, Q1–Q3, 2019

Number of deals

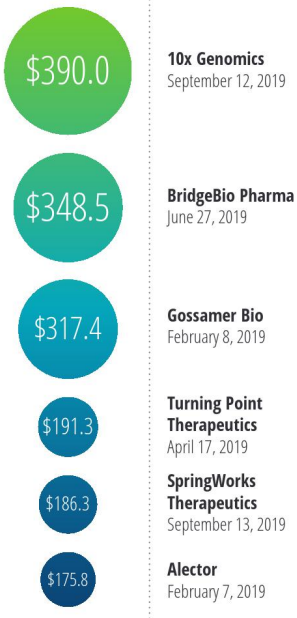
Source: *Pharmaceutical products and market*, Statista, October 15, 2019.

Four drug developers entered the US public market in 2019 with valuations of at least US$2 billion, the strongest run of IPOs of this size in this sector (figure 5).

FIGURE 5

Leading biotech IPOs of 2019

In US$ millions



Sources: EvaluatePharma; Kevin Dowd, "2019 and 12 big things: IPOs, SoftBank and more with a unicorn CEO," Pitchbook, November 10, 2019.

However, there appears to have been a big ballooning of private valuations over the last few years.[64] Along with a rocky stock market in the third quarter of 2019, many companies are being forced to accept lower valuations, which some experts say may be more realistic (figure 6).[65]

Medtech's billion-dollar era

As of the first half of 2019, the medtech sector already surpassed 2018's M&A total, including eight multibillion-dollar deals for a total of US$29.5 billion.[66] The four largest deals concerned businesses that supply hospitals. Private equity also looks to be increasing its interests in medtech. Four deals of the top 10 in 2018, and two in the first half of 2019, fell to private equity firms.[67]

The first half of 2019 also saw the largest VC round ever in medtech and biopharma going to Verily Life Sciences, Alphabet Inc.'s research organization and a former division of Google X. The US$1 billion venture round was only Verily's second reported round. Overall, however, early investment in medtech companies is falling considerably, as is the number of venture rounds per quarter.[68] Medical device deals in the third quarter of 2019 totaled US$10.78 billion globally.[69]

TECHNOLOGY ACQUISITIONS AND TRENDS

In 2019, life sciences companies announced deals to acquire 37 technology companies. As of September, more than half the deals were still pending. Software companies make up the majority of acquisitions at 18, followed by advertising and marketing companies (five) and IT consulting and services (four). Acquirers include six pharmaceutical companies, two biotech companies, and 29 health care equipment and supply companies.

Some notable deals include:

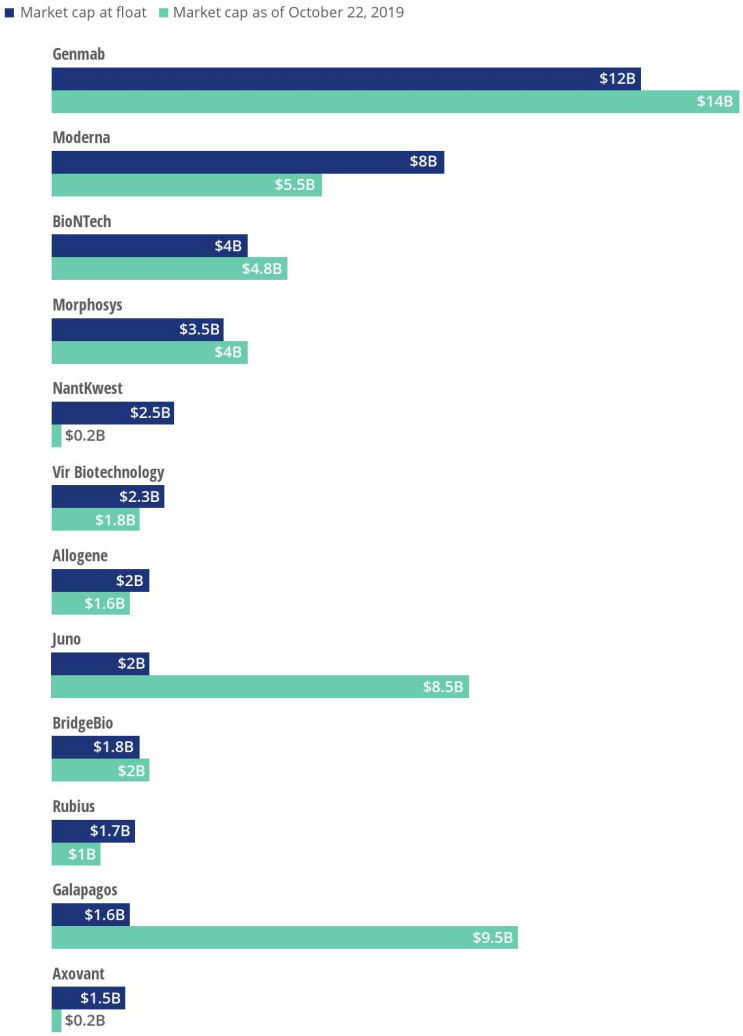
- France-based Dassault Systèmes' US$5.8 billion acquisition of US-based Medidata Solutions, with the goal of creating an end-to-end scientific and business platform for life sciences.[70]

- US-based Thermo Fisher Scientific's acquisition of HighChem, a Slovakia-based developer of mass spectrometry software that can analyze

FIGURE 6

Biotech's blockbuster flotations in US markets

In US$ billions



Source: Amy Brown, *Bloated on arrival? Biotech's weightiest new issues*, EvaluatePharma Vantage, October 22, 2019.

complex data and identify small molecules in pharmaceutical and metabolomics laboratories.[71]

- Atrys Health's acquisition of Real Life Data SLU, both based in Madrid, Spain. Real Life Data specializes in health big data and real-world evidence solutions that are expected to enhance the work of Atrys in predictive medicine and deepen knowledge about the evolution and dimension of pathologies, trends in diagnoses, and treatments.[72]

Rise of health-based technology unicorns

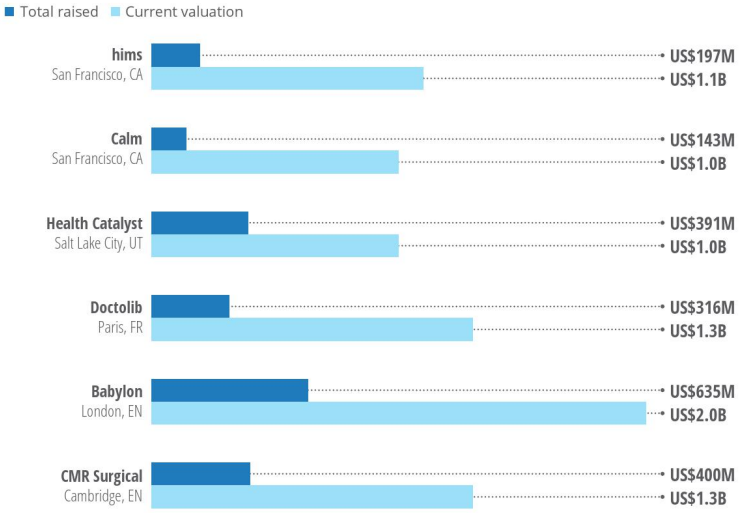
As of November 2019, United States and European venture capitalists hold a record US$144 billion in uninvested capital.[73] Some experts believe the IPO market for US-listed tech companies is in a "megacycle," and despite some companies not meeting expectations, 2020 may be the fifth year of growth in the tech IPO market.[74] In the first three quarters of 2019, a number of health-based technology companies joined the ranks of unicorn[75] status, which are privately held startups with a value over US$1 billion[76] (figure 7).[77]

The direct listing: A new way to raise capital

In late 2019, the New York Stock Exchange (NYSE) filed with the US Securities and Exchange Commission (SEC) to allow companies going public to raise capital through a direct listing, instead of an IPO.[78] The direct listing model will allow companies to list existing shares held by investors on a public exchange—rather than offering new shares for trading, as is done in an IPO. This model allows bypassing intermediaries and avoids dilution of a company's existing stock.

FIGURE 7

Health-based technology unicorns that passed US$1 billion in valuation in 2019



Note: Data as of December 6, 2019.
Source: Andy White and Priyamvada Mathur, "Meet the unicorn class of 2019," PitchBook, March 5, 2019.

Some experts say many more companies, in particular, technology companies,[79] may be considering direct listings as an avenue for going public in 2020.[80]

Software licensing trends

Compliance, risk management, and product life cycle management (PLM) software applications are likely to continue playing a dominant role in life sciences.[81] The life sciences applications market is expected to reach US$8.9 billion by 2022, compared with US$7.7 billion in 2017, at a compound annual growth rate (CAGR) of 2.9 percent.[82]

In 2019, innovators appear to be making investments in new technologies for drug discovery and real-world evidence.[83] Computational medicine has been pivotal in streamlining the process of drug development, and growth has been supported by funding provided by the US National Science Foundation and the US National Institutes of Health. The computational medicine and drug discovery software market is expected to grow at a CAGR of 5.1 percent from 2018 to 2023, and is expected to reach US$7.87 billion by the end of 2023.[84]

Cloud investments

In 2019, cloud investments became one of the top priorities.[85] As cloud technology continues to mature, regulated organizations, including life sciences, have not only begun trusting the technology more, but seeing it as a competitive advantage.[86]

Cloud migration and data modernization are mutually reinforcing trends, and Deloitte research shows they are reaching a tipping point among

FIGURE 8

Software licensing deals/partnerships through Q3 2019

COMPANY	DEALS WITH SOFTWARE COMPANIES	
AstraZeneca	ProteinQure	Multiyear collaboration to use quantum computing for drug discovery
BMS	Concerto HealthAI	Analysis of real-world oncology data to generate insights and real-world evidence
Gilead	Insitro	Use Insitro's platform for developing disease models for nonalcoholic steatohepatitis
Janssen	Iktos	Use Iktos's virtual design technology for discovery of small molecules
Merck	Iktos	Use Iktos's virtual design technology for discovery of small molecules
Novartis	Microsoft	Develop an AI innovation lab for designing personalized therapies
Pfizer	CytoReason	Standardization and organization of Pfizer's data for integration with the company's immune system model
Sanofi	Google	Develop a virtual innovation lab for analysis of real-world data

Source: "33 pharma companies using artificial intelligence in drug discovery," BenchSci Blog, October 2019.

large and medium-sized businesses. The leading drivers of cloud migration are security and data protection.[87] From 66 life sciences and health care companies surveyed by Deloitte, 85 percent are implementing or have fully implemented data modernization.

In 2020, more enterprise resource planning (ERP) buyers are expected to move to the cloud,[88] and businesses that use SAP solutions are making the move to take advantage of cloud flexibility and scalability.[89] Worldwide public cloud service revenue is expected to grow 17 percent in 2020.[90]

RETURN ON CAPITAL AND DELIVERING VALUE

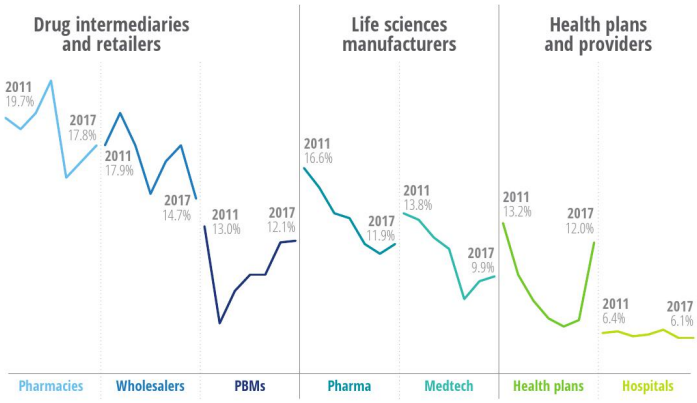
Deteriorating return on capital

Return on capital (ROC) provides insights for organizations that are considering potential partners and new opportunities. While the traditional focus is on profits, margins, and revenue, ROC can provide a fresh perspective. It could be one of the key metrics that matter for 2020—providing new understanding of the efficiency of allocating capital under control to drive profitability.[91]

Deloitte's research discovered that ROC declined for drug intermediaries and retailers, health plans and providers, and life sciences manufacturers, from 2011 to 2017 (figure 9). Life sciences companies saw the biggest drop—from 17 percent in 2011 to 11 percent in 2017. ROC for medtech companies fell from 14 percent to 10 percent in the same period. Generally, life sciences companies had higher profit margins than companies in other sectors but demonstrated lower ROC than other organizations in the health care ecosystem, such as drug intermediaries and retailers, over the seven-year period.[92]

FIGURE 9

Return on capital performance in life sciences and health care nosedived between 2011 and 2017



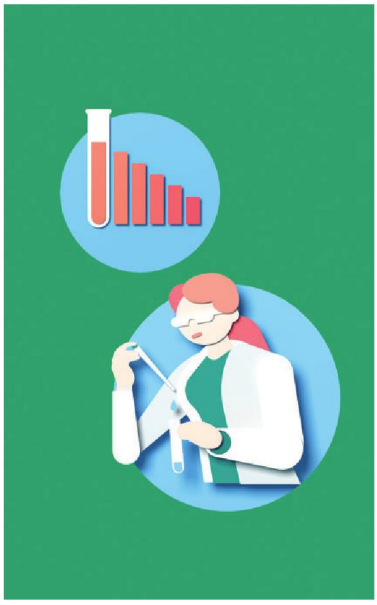
Sources: Teresa Leste, Yakir Siegal, and Maulesh Shukla, *Return on capital performance in life sciences and health care: How have organizations performed and where are best bets going forward?*, Deloitte, April 30, 2019.

Pricing pressure was a key factor for declining ROC for medtech companies, in addition to lower R&D productivity, according to Deloitte research. Hospital systems are now tasked with more procurement decisions and not individual providers. As hospital systems drive harder bargains, competing solely on price has led to ROC deterioration.[93]

Specialization drives higher ROC

Deloitte research shows life sciences and medtech companies that focused on specialty areas had the highest ROC in 2017. In pharma specialties, ROC was highest for:

- Antivirals, 26 percent
- Musculoskeletal, 20 percent
- Oncology, 18 percent[94]



In medtech specialties, ROC was highest for:

- Robotic surgery, 21 percent
- Cardio, 20 percent
- ENT, 20 percent
- In vitro diagnostics, 15 percent[95]

In 2020, specialization is expected to remain an area of opportunity. Services and solutions that create value by improving outcomes and lowering costs could be another. R&D was found to be a source of diminishing ROC, especially having fewer assets in the late-stage pipeline and lower potential sales per asset.[96] Over the seven-year period, the average cost to develop a drug doubled.[97]

In a future with interoperable and real-time data, coupled with the full range of new technologies, it is likely that the greatest returns will likely accrue to organizations that successfully mine the data to deliver personalized solutions. Personalized solutions that meet consumer demands and keep people well and functioning at their highest potential can deliver value.[98]

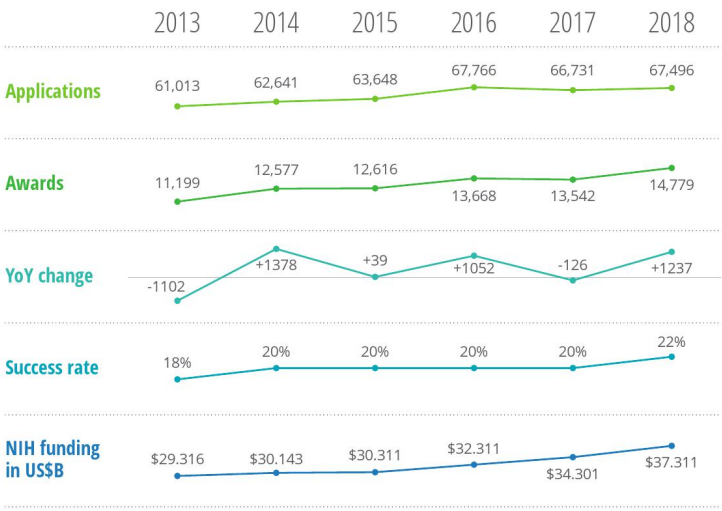
GRANT AND ACADEMIC RESEARCH TRENDS

The total NIH appropriation for biomedical research is US$39.2 billion for FY2019.[99] Fiscal issues significantly impact the amount of federal investment.[100] Increases help maintain and grow research capacity by offsetting inflation and expanding research.[101] However, the proposed FY2020 budget is US$34.4 billion, a decrease of approximately US$4.8 billion or 12.2 percent.[102] This decrease shifts the upward trend in funding realized every year since 2013 (figure 10). The number of awards is also likely to decrease and may have an impact on innovation.

The NIA's FY2019 budget of US$3.08 billion is almost 8 percent of the total NIH budget. Between

FIGURE 10

NIH research grants: Competing applications, awards, and success rates, 2013–2018



Note: Success rates measure the likelihood of a research grant being awarded funding.[103]

Sources: *NIH Data Book*, Report 159, US National Institutes of Health, January 2019 and National Institutes of Health Funding, FY1994–FY2020, Congressional Research Service, April 2019.

FY2014 and FY2019, NIA funding increases for Alzheimer's disease and related dementias research totaled US$1.7 billion.[104] The NIH supports a total of 288 various research/disease categories based on grants, contracts, and other funding mechanisms.[105]

More than 80 percent of the NIH budget supports extramural research conducted at over 2,700 organizations.[106] NIH research typically produces significant return on investment for local businesses across the United States. On average, every NIH grant creates seven high-quality jobs.[107] Johns Hopkins University received the single largest award for a US research institution in 2019 at US$738.9 million (figure 11).[108]

Recent research shows that federally funded cancer treatment trials may fill an important gap in clinical research by seeking answers to treatment questions that might otherwise not be explored. Researchers were surprised to find that 43 percent of the trial results studied had negative results, and half of those reaffirmed standards of care compared to experimental therapies.[109]

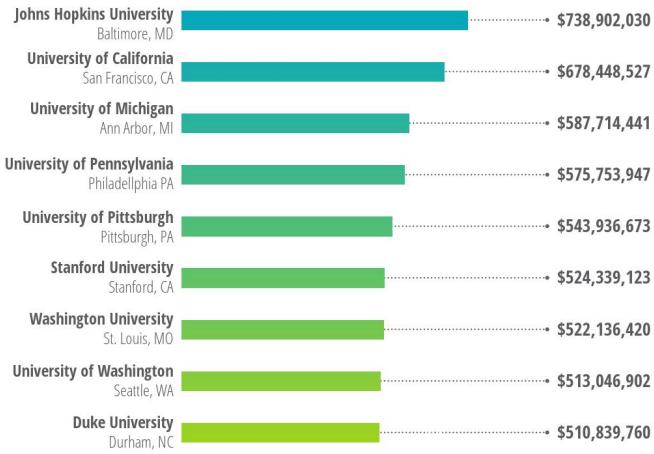
SHIFTS IN THERAPEUTIC FOCUS

Pipelines to come

R&D spend is forecast to grow at a compound annual growth rate (CAGR) of 3 percent over the 2019–24 period.[110] In 2019, there were 16,181 drugs in the pharmaceutical pipeline, compared with

FIGURE 11

Leading NIH research awards by location and organization for 2019



Source: US National Institutes of Health, "Research portfolio online reporting tools (RePORT)," data as of October 14, 2019.

15,267 in 2018, an increase of almost 6 percent. The pipeline includes all drugs being developed by pharma companies—from preclinical and other stages of clinical testing to regulatory approval and launched drugs (i.e., still in development for additional indications or markets).[111]

Therapy areas with the largest increase in activity over the past year are focused on oncology; amyotrophic lateral sclerosis (ALS) and other degenerative musculoskeletal conditions; rare diseases related to the gastrointestinal (GI) tract; and nonnarcotic pain treatments. Since 2013, the number of oncology drugs increased by 63 percent, and oncology contributes to 40 percent of the clinical development spend. Oncology is predicted to have close to 20 percent of the market share of pharmaceutical sales by 2024.[112]

Since 2013, pain and dermatology drugs rose more than 50 percent, but represent just under 6 percent of the total pipeline each. The number of vaccines under development declined by 4 percent.[113]

In 2020, the shift is expected to continue toward rare diseases and treatments for unmet needs. The number of next-generation cell, gene, and nucleotide therapies more than doubled over the past three years. These new approaches to treating and curing disease continue to attract attention and investment.[114] But uptake has been slower than expected, mostly due to the high cost of new treatments and the challenges in coverage and reimbursement faced by commercial and public payers.[115]

This creates a need for new financing solutions and reimbursement models that can ensure appropriate patient access to needed treatments, increase affordability for payers, and sustain private investment in innovation.[116] MIT's FoCUS Drug Development Pipeline analysis found that annual reimbursements for cell and gene therapies

could reach between US$20 billion to US$30 billion by 2031.[117]

Only an estimated 5 percent of rare diseases have a pharmacotherapy, and governments worldwide continue to support their development.[118] Next-generation therapies still represent less than 10 percent of the total late-stage R&D pipeline.[119]

Antibiotics are another area of unmet need but may not be profitable enough to develop, and some pharma companies appear to be exiting the field.[120] As of Q2 2019, approximately 42 new antibiotics with the potential to treat serious bacterial infections were in clinical development. However, only one in five infectious disease products that enter phase I clinical trials on humans will be approved for patients.[121]

Organizations like the Bill & Melinda Gates Foundation are actively working to address the challenge of antimicrobial resistance (AMR) in developing countries.[122] Support is likely needed for new financial stimuli, including help from the public sector.[123] In India, Pfizer Inc. is partnering with the Indian Council of Medical Research and working to change the way antibiotics are prescribed and used. Behavior change is expected to be a key part of the strategy.[124]

Despite high levels of pipeline activity, oncology R&D continues to face significant risk of failure and long development times. The oncology composite success rate dropped to 8.0 percent in 2018, compared with 11.7 percent in 2017.[125] There is a lot of competition in clinical trial recruitment for oncology due to a finite number of patients and an increasing number of treatment options. In 2018, 28 out of 33 pharma companies with global pharmaceutical sales over US$5 billion had large and active oncology pipelines.[126] In 2020, a promising shift may come from combination therapies in oncology and what they could potentially unlock, treating different types of tumors.[127]

One of the most valuable products in the pharmaceutical pipeline is projected to be Vertex's triple combination, VX-659/VX-445 + tezacaftor + ivacaftor, a transformative medicine for cystic fibrosis. It is demonstrating a net present value (NPV) of US$20 billion.[128]

Small vs. large molecule development

In 2019, small molecules dominated the pharmaceutical pipeline with 22 US FDA approvals compared with eight large molecule (biotech) approvals as of October 22, 2019.[129] The number of large molecules being investigated in 2019 increased significantly compared with 2015.[130] In 2019, four out of every 10 drugs under development are biotech-derived. The growing demand for personalized medicine and orphan drugs is driving R&D investments in large molecule products.[131]

TRACKING THE GROWTH OF NEW AND EXPANDED MANUFACTURING FACILITIES

A flurry of acquisitions for cell and gene therapy manufacturing facilities

In 2020, manufacturing is expected to be a key differentiator for gene therapy companies. Contract manufacturing organizations (CMOs) and contract development and manufacturing organizations (CDMOs) are adding capacity.[132] Big pharma companies are also building their own facilities and buying capacity from smaller companies.[133]

The demand for additional manufacturing capacity will likely be exacerbated by accelerated regulatory approvals. By 2025, the US FDA expects it will be approving 10 to 20 cell and gene therapy products a year.[134] Phases of development are advancing so quickly that in order to be ready for commercialization, companies should be considering manufacturing at the beginning of development.[135] While the number of facilities are growing, experts say one of the biggest challenges will be staffing these facilities with enough trained and qualified personnel.[136]

Notable manufacturing investments for cell and gene therapies include:

- Cambrex Corp. acquired Avista and its four facilities (three in the United States, one in Scotland) for US$252 million to become an integrated CDMO.[137] Cambrex was then acquired for US$2.4 billion by an affiliate of the Permira funds.[138]
- Catalent Inc.'s US$1.2 billion acquisition of Paragon Bioservices Inc. in Baltimore, Maryland, a viral vector CDMO for gene therapies.[139]
- Switzerland-based Lonza Group Ltd. doubled its production capacity for viral gene and virally modified cell therapy products with a new 300,000-square-foot facility in Pearland, Texas.[140]
- France-based Novasep invested US$30 million in a viral vector facility on its site in Seneffe, Belgium.[141]
- Brammer Bio is installing clinical and commercial gene therapy manufacturing capabilities at its 66,000-square-foot facility in Cambridge, Massachusetts. It was recently acquired by Thermo Fisher for US$1.7 billion.[142]
- LakePharma Inc. in California and Oxford BioMedica Plc in the United Kingdom have also invested in viral vectors.[143]
- Precigen is adding a 5,000-square-foot facility for gene and cell manufacturing in Maryland.[144]
- Pfizer Inc. acquired Bamboo Therapeutics in Chapel Hill, North Carolina, along with a phase I/II gene therapy manufacturing facility.[145]
- Bluebird Bio Inc. opened its first wholly owned manufacturing facility, a 125,000-square-foot facility in Durham, North Carolina.[146] Bluebird received approval from the European Medicines Agency (EMA) to manufacture its autologous gene therapy, Zynteglo, in Europe.[147] Its CDMO is German-based apceth Biopharma GmbH, recently acquired by Hitachi Chemical. Hitachi has plans to build a regenerative medicine business in the United States, Europe, and Japan.[148]
- Moderna Therapeutics opened a 200,000-square-foot manufacturing facility in Norwood, Massachusetts.[149]
- Novartis is expanding its gene and cell therapy manufacturing with a new production facility in Stein, Switzerland, and adding another 38,750 square feet by acquiring CellforCure.[150] It is also cutting costs to finance new therapies, shedding eight facilities and revamping another eight.[151]
- Cellectis is building an 82,000-square-foot commercial manufacturing facility in North Carolina for its allogeneic CAR-T products and a 14,000-square-foot facility in Paris, France, for its allogeneic gene-edited CAR-T cell (UCART) products.[152] It also has a manufacturing servicing agreement with Lonza for its facility in Geleen, the Netherlands.[153]
- Sanofi is retrofitting a vaccine plant in France into a gene therapy manufacturing operation.[154]

API manufacturing acquisitions and shutdowns

Active pharmaceutical ingredient (API) manufacturers appear to have been a key target for CMO M&A in the 2015–17 period, making up 30 percent of acquisitions.[155] In 2018, a number of large molecule API CDMOs invested in single-use production capacity.[156]

- Denmark-based AGC Biologics added a 2,000L single-use bioreactor at its therapeutic protein manufacturing facility in Berkeley, California.

- Avid Bioservices is developing a single-use biomanufacturing process for its client, Acumen Pharmaceuticals, in Tustin, California.
- China-based WuXi Biologics is building an API biomanufacturing facility in Ireland.[157]

Environmental challenges appear to also be narrowing the pool of API suppliers, as a number of high-polluting API manufacturers were shut down by the Chinese government.[158]

QUESTIONS TO CONSIDER FOR CREATING VALUE IN 2020

- How can you create a more holistic patient experience?
- How can you reduce complexity in the patient experience?
- What types of technologies can improve the patient experience?
- What steps can you take to increase the participation of women, minorities, and older patients in clinical trials?
- Are you involving patients and patient advocacy groups in designing the patient experience?
- How can you evolve work culture around capabilities?
- How can you measure the effect of workforce experience on customer experience?
- Do you believe health care information (particularly in the United States) will become available as part of open systems or stay closed and proprietary?

Opportunities and efficiencies

Accelerating R&D with technology

INTELLIGENT DRUG DISCOVERY AND THE EXPLOSION OF AI STARTUP

Considerable growth is expected for the AI market in biopharma. The market is predicted to increase from US$198.3 million to US$3.88 billion between 2018 and 2025, at a CAGR of 52.9 percent. AI in drug discovery alone accounted for the largest market size, increasing from US$159.8 million to US$2.9 billion in the forecast period.[159]

It appears that a new breed of startups is leading the way in how new drugs are discovered and developed.[160] As of December 2019, almost 180 startups were involved in applying AI to drug discovery (figure 12).[161]

Almost 40 percent of these AI startups are specifically working on repurposing existing drugs or generating novel drug candidates using AI, machine learning, and automation.[162] Recursion Pharmaceuticals, based in Salt Lake City, uses AI and automation to test thousands of compounds on hundreds of cellular disease models.[163] Each week, the company generates 65 terabytes of data[164] in search of new compounds that can disrupt disease without harming healthy cells.[165] Since 2017, Recursion has two drugs in clinical trials[166] and rare disease deals with Takeda Pharmaceutical Ltd. and Sanofi. In July 2019, Recursion raised an additional US$121 million in series C funding.[167]

FIGURE 12

Close to 180 startups applying AI to drug discovery

No. of AI startups	Area of AI drug discovery
59	Generating novel candidates
29	Aggregating and synthesizing information
13	Designing drugs
12	Understanding mechanisms of disease
10	Validating and optimizing drug candidates
9	Recruiting for clinical trials
9	Designing clinical trials
9	Designing preclinical experiments
8	Establishing biomarkers
8	Repurposing existing drugs
7	Optimizing clinical trials
5	Running preclinical experiments
4	Analyzing real-world evidence and publishing data
1	Generating data and models[168]

Source: Simon Smith, "177 startups using artificial intelligence in drug discovery," BenchSci Blog, December 3, 2019.

Instead of screening millions of molecular structures, Hong Kong-based InSilico Medicine uses a creative AI algorithm for de novo

small-molecule design. Based on existing research and preprogrammed design criteria, Insilico's deep learning system can find potential protein structures at a lower cost and in record time. In September 2019, InSilico published landmark research in *Nature Biotechnology* demonstrating that one leading drug candidate produced favorable pharmacokinetics in mice for fibrosis in 21 days at a cost of only US$150,000.[169] Insilico also raised US$37 million in series B funding from China-based investors.[170]

According to Deloitte research, the average cost of developing a drug is approximately US$2.1 billion.[171] In the future, a 10 percent improvement in the accuracy of predictions[172] could lay the groundwork for saving the pharmaceutical sector billions of dollars and years of work.[173] Drug discovery and preclinical stages could be sped up by a factor of 15 and enable more competitive R&D strategies.[174]

AI COLLABORATION, A KEY FOR BIG PHARMA INNOVATION

As of November 2019, 34 pharma companies are using AI for drug discovery, including, by partnering with AI startups.[175] Over the next year, competition for AI talent will likely be fierce, and pharma companies should not let traditional thinking and legacy cultures put them at a disadvantage.[176]

Alliances have begun to form to coordinate and advance the adoption of AI in R&D. Cloud computing could help leaders extend collaboration with other biopharma companies, smaller biotech companies, research laboratories, and academic institutions spread across the globe.[177]

At the same time, pharma companies are leveraging partnerships to explore AI-driven R&D, and many are laying the groundwork for more advanced data strategies. Novartis is looking to maximize the wealth of its clinical data. It has seen some success with STRIDE, its systems transformation project for a data system that can be easy to access, use, and analyze. Its Data42 project is leveraging the power of data analytics, machine learning, and AI to find leads for possible new drugs.[178]

Tech giants are also making their presence felt in the technology race. Google's DeepMind made a major advance on one of the most important problems in biochemistry at the end of 2018. AlphaFold, its AI algorithm, combined two techniques that were emerging in the field and beat established contenders in a competition, on protein-structure prediction, by a surprising margin. While pharma scientists were upended by the discovery, observers believe, outside disruption will lead to newer advances.[179]

The ability of AI protein-folding algorithms to solve structures faster than ever is expanding and may speed up the development of new drugs.[180] Over the next decade, patients can expect these developments to have a significant impact on treatment options, particularly in areas where there is no treatment currently.[181]

The lifeblood of biomedical research and innovation is rich health care data. Today, despite the increasing amounts of health care data generated, most of this data is inaccessible to other organizations for collaboration due to a myriad of reasons, including security concerns, technology constraints, and business-model challenges. These challenges mean that the health care ecosystem is not fully benefiting from the insights of the secondary use of all this digital health data. This slows the pace of health care innovation and limits the potential to improve the lives of patients and our medical system.

To address this issue, Amazon Web Services (AWS) launched Data Exchange, a service for unlocking many data sources that have traditionally been locked in silos across multiple organizations. The goal is to provide health care stakeholders with a

scalable and secure service to create new collaborative business models and reimagine how they approach research, clinical trials, pharmacovigilance, population health, and reimbursement.[182]

TRENDS IN APPROVALS

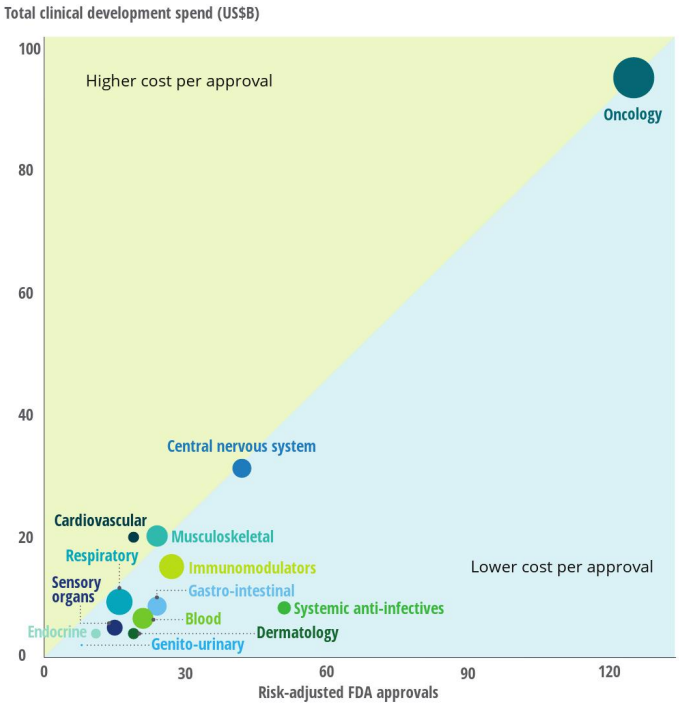
According to a 2018 study from the MIT Sloan School of Management, almost 14 percent of all drugs in clinical trials eventually win approval from the US FDA. This number is higher than initially believed by observers in industry and academia. While the overall success rate for all drug development programs did decrease between 2005 and 2013 from 11.2 percent to 5.2 percent, the decline slowed down after 2013, around the time the US FDA began approving more novel drugs.[183] More than half of the approvals were for rare diseases in 2018.[184]

Seventy-three percent of new drugs approved by the US FDA went through an accelerated approval

FIGURE 13

Clinical development spend vs. risk-adjusted FDA approvals by therapy area

Circle area = total NVP (US$ billions)



Source: *World Preview 2019, Outlook to 2024*, EvaluatePharma, June 2019.

process in 2018. From 2013 to 2018, Breakthrough Therapy Designations increased from four to 39, and Fast Track Designations increased from 21 to 85. Most drugs approved through the accelerated approval process treat conditions that are debilitating or deadly, and have few or no other treatments. Fast-tracking new drugs is becoming "a new normal," but there are still concerns over quality, safety, and costs.[185]

China's overhaul of regulations in recent years brought a fast-track approval process and a potential local study waiver for products targeting rare diseases or diseases with substantial unmet needs. Since then, China has experienced exponential growth in new approvals and a significant reduction in drug lag, compared with the US FDA and EMA (figure 14).[186]

In Europe, the fast-tracking approval process is called PRIME, PRIority MEdicines. A recent two-year study on PRIME by the EMA found that 83 percent of approved medicines concerned rare diseases and 44 percent were treatments for pediatric patients.[187]

EFFECTS OF ACCELERATING APPROVALS

Early focus on commercially viable supply chain

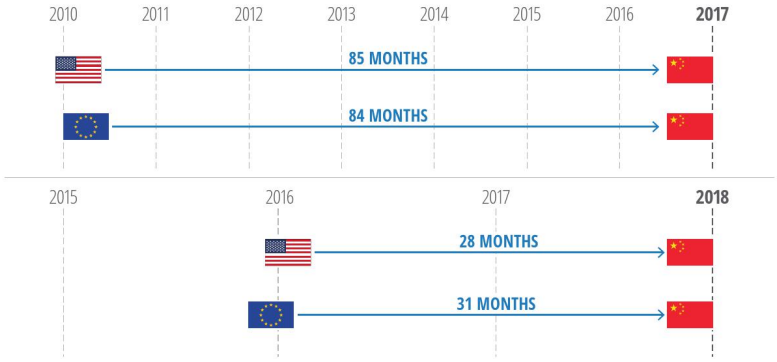
Beginning in 2020, the US FDA anticipates 200 new applications for gene and cell therapies per year. To gear up for this wave, the US FDA is hiring 50 new clinical reviewers.[188]

> "In contrast to traditional drug review, where 80 percent of the review is focused on the clinical portion of that process, and maybe 20 percent is focused on the product issues, I'd say that this general principle is almost completely inverted when it comes to cell and gene therapy."
>
> — Scott Gottlieb, MD, former commissioner, US FDA[189]

FIGURE 14

Chinese Food & Drug Administration (CFDA) gave more new approvals and reduced drug lags compared with US FDA and EMA (in months)

Drug Lags Compared to FDA and EMA (in months)



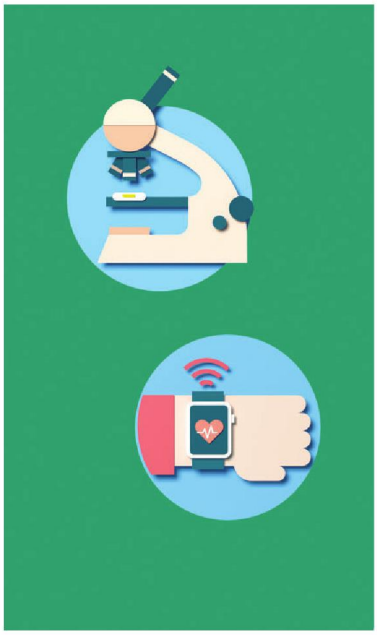
Source: David Xie, Xiaofeng Li, and An Li, *The rewards of regulatory change: Launching innovative biopharma in China*, Deloitte Insights, April 18, 2019.

Accelerated regulatory pathways require commercially viable supply chains to be in place at the start of a phase I/II program. If later in the life cycle there are changes to the manufacturing processes, analytical methods, or supply sites, this can add complexity.[190]

Fast-tracking drugs and medical algorithms

The number of approvals for proprietary medical algorithms continues to rise.[191] In September 2019, the US FDA approved an AI algorithm embedded on-device. The AI screening tool, known as Critical Care Suite, works with portable X-rays to rapidly screen for a collapsed lung and is licensed by UCSF Innovation Ventures to GE Healthcare.[192]

The state of AI in medical device development is evolving. While the US FDA controls the regulatory framework in the United States, the European Union (EU) has several reforms affecting medical devices, including General Data Protection Regulation (GDPR), NIS Directive (for network and information systems and cybersecurity), Medical Device Regulation (MDR), and In Vitro Diagnostic Medical Device Regulation (IVDR).[193]



The new EU MDR is slated to go into effect in May 2020. The regulation will impact combination products, in particular, where the drug component is principal to the function of the device, e.g., insulin injector pens.[194]

Faster reviews in US FDA Pre-Cert Program testing phase

The US FDA's Pre-Cert pilot program for regulating software as a medical device (SaMD) is currently in its testing phase. In a mid-year 2019 report, the agency compared its new Pre-Cert pathway to traditional review and found favorable results. The agency will continue testing with new submissions.[195]

Creating operational efficiencies

MANUFACTURING TRENDS AND PROCESS IMPROVEMENTS

Better tracking via smart factories (automation, sensors, and the Internet of Things [IoT])

The demand for small-volume, personalized medicines is driving operations away from large-scale bulk production to multiproduct facilities that require meticulous tracking. There has always been pressure to get drugs to market faster, while maintaining compliance and data integrity. Smart factories for the future may offer digital automation solutions, industrial IoT connectivity, and flexible manufacturing processes.[196] With a digitized core, including intelligent automation, a company may be able to streamline the number of

days it takes to release a drug product from approximately 100 days to seven.

Medtech companies also have the potential to drive efficiencies and tackle challenges by applying solutions such as IoT, machine learning, additive manufacturing, and augmented reality.[197] Applications in the Industrial Internet of Things (IIoT) can connect and power digital supply networks (DSNs) that inform better decision-making.[198]

Companies can complement and expand the classical functionalities provided by IT (e.g., enterprise resource planning [ERP] systems) while enabling a full integration between IT and operations technology (OT). These technologies could positively drive change throughout each stage of the supply chain, ultimately leading to increased value delivered to the end customer or patient.[199]

Focus on simple processes for early success

Life sciences and medtech companies have increasingly digitized operations to address inefficiencies, and best practice suggests focusing on simple processes before taking on more complex processes. Two areas ripe for advances in technology are inventory and logistics management and warehouse operations.[200]

Tracking productivity in real time with augmented reality

As enterprise manufacturing becomes more complex, biopharma and medtech companies could benefit and drive efficiency, as well as reduce the risk of human error, with new technologies such as AI and augmented reality (AR). AI and AR tools are increasingly being incorporated into labs, processing lines, and manufacturing suites to increase safety, reliability, and efficiency. For workers, they can serve as performance-enhancing tools.[201]

Depending on the use case and facility, users could engage an AR experience via a headset, mobile device, or tablet. As headsets offer hands-free operation, workers would be able to access data or continue a task without interrupting workflow.[202]

AR platforms' ability to solve problems in real time can help reduce the potential for error and increase productivity. Workers could access training in real time, e.g., accessing a training tutorial on the spot to better understand a procedure or task, or even engage a remote expert across the globe to solve problems quickly and more cost-effectively.[203]

As AR is expected to continue gaining traction in the biopharma and medtech segments in 2020, it may become part of more core enterprise software, such as customer relationship management (CRM) systems. Organizations with the ability to address customer or vendor concerns in real time can create a more personalized and expeditious experience.[204]

Focus on manufacturing quality and agility with product data management

Data-driven manufacturing is generating more excitement heading into 2020 compared with new manufacturing technologies. With digital innovation providing a renewed focus on quality, companies are revisiting their approach toward managing the cost of quality and compliance. Even with decades-old processes, data can help them start seeing valuable insights in a matter of weeks.[205]

Large tech companies are the new partners bringing in computing power, manufacturing analytics, and advanced supply chain control towers. For example, advanced control towers now provide real-time visibility and powerful AI capabilities to move beyond decision-support to decision-making and autonomous control. Tech companies, like McLaren Applied Technologies, can run millions of scenario simulations based on a "digital twin" of a physical business to improve operations.[206] An important first step in these types of technology deployments should be choosing a

business segment with a high value or business impact, where success can serve as a benchmark for subsequent implementations.

In 2020, manufacturing will likely become more agile, and new benchmarks could be built around operations agility. To be truly successful, leaders could look at freeing up cash from R&D and getting control of the cost of goods sold (COGS). Cell and gene therapy manufacturing, in particular, needs to focus on bringing down COGS. Small scale, manual processes require large footprints, and industrializing complex therapies may rely partly on:

- Applying lessons learned in other areas of drug manufacturing
- Adopting new technologies and approaches
- Employing basic process engineering

Companies looking to improve will likely need better insights into data being fed back into the development process and their products over the entire life cycle. Better decision-making can result from connected planning platforms where predictive analytics enable speed and agility.

Demand for gene and cell therapy manufacturing spurs expansion

The rapid progression of gene and cell therapies through clinical trials appears to be driving an increasing demand for manufacturing facilities. As of Q3 2019, more than 3,300 phase-II through phase-IV cell and gene therapy trials were underway (figure 15).[207]

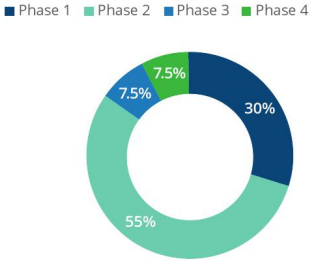
As companies transition from clinical to commercial, product manufacturing becomes a crucial issue.[208] Cell and gene therapy manufacturing is highly complex—however, development times are typically shortened to three or four years, compared with eight on average for biologics.

Manufacturing for autologous therapies is especially riddled with complexity and very short timelines, and quality cannot be compromised.[209] Unlike traditional small molecule and protein drugs, gene therapies manufactured with patients' cells are individually manufactured on demand. Chimeric antigen receptor T-cells (CAR-T) manufacturers at commercial scale are typically challenged with procuring good quality vectors, minimizing variability in cell production, and capabilities for cryopreservation.

Even after manufacturing, the supply chain and distribution model for autologous cell therapies can be distinct from traditional pharma and requires an entirely new approach. Challenges may include chain of identity/custody tracking, cold chain logistics, as well as the need for white-glove service to ensure product integrity and timely delivery. Some early-stage companies have been buying preestablished facilities or building in-house facilities from the ground up, while others are increasingly exploring outsourcing options.

FIGURE 15

Early stage clinical trials dominate cell and gene therapy development activity



Source: *The Future of Cell and Gene Therapy*, Signal Analytics, November 2019.