



2021 global life sciences outlook

Possibility is now reality, sustaining forward momentum

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Overview and outlook

AS A RESULT of the pandemic, the door to innovation was thrust open, and we all rushed in. Novel technologies that were expected to advance over a decade were adopted in a few months, weeks, and sometimes, even days—an unprecedented pace of change. New ways of working and living were suddenly possible because change was necessary, not optional.

Amid the tragic consequences of COVID-19, life sciences and medtech companies emerged as lights in the darkness. Decades of scientific work and investment seemed to be overnight successes. The heroic dedication of health care providers was met by the fastest novel vaccine development in history. Traditional competitors partnered to accelerate research and manufacturing. When one company failed, it joined the other to accelerate the development and manufacture of a successful vaccine. Governments, retail pharmacies, health systems, payers, and nonprofits are working together to provide widespread distribution and administration.

With more confidence and success, comes more responsibility. Pharmaceutical innovation is saving the world,¹ and the sector is on its front foot. Now is the opportunity to build more trust, reach more people, and do greater good.

The 2021 Global Life Sciences Outlook looks at the many ways COVID-19 accelerated change for the sector, the changes that are likely to stay, and what can be reimagined and made better.

We discuss:

- Work, workplace, and workforce being redesigned and meeting individual needs
- Accelerated digitization, expanding new points of care and new roles for pharma and medtech
- A more customer-centric commercial model, meeting physicians where they are, on their terms, and through more meaningful interactions
- New types of collaborations and clinical trials that are reshaping research and development
- How companies can shorten development times by thinking more like a regulator
- How cross-border reliance intensifies the need for supply chain visibility and reshoring options
- How the sector is advancing humanity, and how it can better measure its progress

How can biopharma and medtech companies sustain this forward momentum? Biopharma and medtech companies should embrace the pace of change, innovations, and norms adopted over the past year. Successful organizations will take these lessons—from new ways of working, collaborating, and operating digitally—sustain them, and work to institutionalize them.

In 2021, with a newfound, elevated role in society, the sector can make greater impact toward a more compassionate, equitable world—a world where everyone can truly thrive. *Possibility is now reality.*

“It will take years for us to fully understand the impact that COVID-19 has had on the industry.”²

Redesigning work, workplace, and workforce, while meeting individual needs

Work meets real life

We all experienced fundamental changes in our work and home lives as a result of the pandemic—and did so almost overnight. In a world disrupted, we became collective problem-solvers, augmented by new technologies, but nonetheless, more human and compassionate. Zoom meetings revealed real life, complete with interruptions by spouses, children, and pets, and that was OK.

We start this report by reflecting on the changes that affected all of us. A hyperconnected world with more and new technologies attracted some but overwhelmed others. How can work be redesigned, made better, and suited to individual, human needs? We cannot create a better tomorrow for everyone, if we cannot meet the needs of the day. Is the future of work we've seen over the past year the same one we want over the next 10 years?

Becoming more human and uber-flexible in how, where, and when we work

Work is in a continuous state of reimagination, and flexibility is more important than ever. In the coming year, organizations should take a more in-depth look at human resources (HR) and its evolving new role—encompassing the entirety of work, workplace, and workforce.³

Lessons learned from the pandemic bring sharp focus to global human capital trends that have been evolving for years—trends toward well-being, reskilling, and *superteams* (humans working with machines).⁴ Human potential is a great untapped asset,⁵ and these lessons reinforce the need to bring a human element into everything an organization does, including working with technology.⁶

HYBRID WORKPLACES: WORKING FROM ANYWHERE

Companies have the opportunity to reassess what work really means and reimagine how work might be done.⁷ In-office and remote work are different *platforms of work*.⁸ No two organizations will have the same needs, and neither will two employees.⁹ Companies are rising to meet the needs of the individual. In July 2020, Novartis moved from *manager-approved* remote work to *manager-informed* remote work. Employees can choose to work how, when, and where they want.¹⁰

No role in life sciences was more affected than the pharmaceutical sales representative. In March 2020, Pfizer instructed all those in customer-facing roles in the United States and Puerto Rico, primarily salespeople, to work remotely and use virtual customer tools.¹¹ Work policies are continuously being reassessed, and remote work now has many classifications.

EXPANDING NETWORK EFFECTS OF WORKING FROM ANYWHERE

2020 saw exponential growth in connectivity through greater use of digital tools, faster (5G) networks, and cloud computing. The ability to connect and work from anywhere will continue to create network effects—expanding access to new talent and new partners, while extending an organization’s capabilities.¹² Today, new ways of collaborating significantly reduce the time, distance, and cost of communications, meetings, and deal-making.

At the *Financial Times* 2020 Global Pharmaceutical and Biotech Conference, Bayer’s Marianne De Backer relayed how Bayer’s US\$2 billion acquisition of AskBio was done virtually; research labs were toured via an iPad. Without ever meeting in person, the deal was consummated in just a few weeks. Prior to the pandemic, De Backer never imagined a deal could be done virtually, let alone so quickly.¹³

“The silver lining of this pandemic has shown that we can do things differently.”

— Marianne De Backer, head of Pharmaceuticals Business Development & licensing, [bayer pharmaceuticals](https://www.bayer.com)¹⁴

FOSTERING A CULTURE OF BELONGING

Not being in the office and working remotely actually produced more connectedness for some workers, and they found leadership to be more accessible. Research finds that 64% of workers want to spend at least some hours in the workplace,

as opposed to working remotely full time—a *hybrid* model of work. Ninety percent of employers say productivity has not suffered with flexible schedules,¹⁵ and some see a rare opportunity for talent acquisition in the current environment. The lack of geographic constraints widens the pool for talent and access to skills.¹⁶

In the coming year, it is essential to find ways to keep the workforce feeling emotionally connected no matter how or where they work.¹⁷ One of the biggest challenges for life sciences and medtech organizations will be fostering a culture of belonging for remote workers.¹⁸ Critics argue that some degree of innovation may be lost in a purely virtual environment, and the need for better remote collaboration and tools will persist.¹⁹

What is a physical space for?

Work from anywhere means real estate needs are shifting. As more people work remotely, organizations are downsizing office space. Some companies are offering “de-location” packages, providing a stipend for new hires to live anywhere of their choosing.²⁰ Others are thinking about repurposing offices as nonwork retreats—for employees who may need a break *from home*.²¹

Life science leaders are reevaluating the future role of the main campus, looking for new ways to maintain culture and drive client innovation. Life science companies could consider repurposing space by inviting ecosystem partners into their traditional office space campuses.

REIMAGINING THE WORKSPACE, FLEX SPACES AND NEW TECHNOLOGIES

The workplace is being reimagined—from virtual workspaces to new types of offsite collaboration.²² New agile spaces designed specifically for teams to work and socialize offsite will grow to accommodate a post-COVID-19 world. One such space is *Wellspire* in Nashville, Tennessee. Not a coworking space, the facility is rented to only one client at a time. Rooms are furnished to accommodate large and small team collaboration across multiple environments—from a living room to a kitchen and dinner table—in addition to the standard conference room.²³

Virtual environments are even being designed to simulate working in the office. *Grouproom.io* is a new technology that allows people to move around virtual spaces and collaborate with others nearby just like in real life. Spatial audio gets louder as one moves closer to colleagues in simulated office spaces and softer when moving away. Collaboration tools, such as whiteboards, Google docs, and Zoom, can be embedded in the platform.²⁴

Collective Minds Radiology is a new virtual radiology workspace. The cloud-based platform for case collaboration is building a global network of collective and artificial intelligence (AI) with humans and machines. A radiologist can securely share a case, including multiple exams per case, with a colleague or group for a second opinion and better diagnosis.²⁵

ACCOUNTING FOR CULTURAL DIFFERENCES

Although experts say that one-fifth of the workforce in advanced economies can work just as effectively from home,²⁶ there are many cultural differences affecting the future of work globally. While Australia became creative and resourceful with remote work amid a strict lockdown, countries in middle Europe struggled. They have a legacy relationship with the office, and virtual work is not part of the culture. This was also true in Japan, where at first, pharmaceutical salespeople resisted the idea of virtual work. In Japan, working remotely is now becoming a “good way of working.”²⁷ In China, flexible work arrangements were made available during the pandemic, and there is little reason to believe this will change.²⁸

Redesigning work for well-being

New ways of working have caused the lines of work and life to blur. It is no longer about work/life balance; work and life are intertwined. Remote work is changing where we work and when we work. Too much screen time can tax mental and physical health.²⁹ As a result of the pandemic, many millennials and Gen Z report experiencing a mental health crisis,³⁰ women are leaving the workforce,³¹ and the drag on our collective mental health³² may be a threat to economic recovery.³³ Employers are specifically asking for more robust mental health products.³⁴

Biopharma³⁵ and medtech companies are expanding mental health resources and promoting well-being.³⁶ Leaders and employees still struggle with how to move beyond health and wellness programs to make well-being part of the culture.³⁷ There is a seismic shift toward behavioral health and meeting the behavioral health needs of workers will be critical to helping workers thrive—and for acquiring new talent.³⁸

Rethink work, workplace, and workforce:

- *How can our company be more flexible, unleash human potential, and meet individual needs?*³⁹
- *How can company culture be maintained, or even enhanced, in a new way of working?*
- *What do we really need a physical space for?*
- *How can work be redesigned for true well-being, not just wellness programs?*⁴⁰
- *How can we better support the emotional and mental health needs of individuals?*
- *How can we foster team innovation in a virtual environment?*



Accelerated digitization: New points of care, new roles for pharma and medtech

Virtual health's acceleration broadens pharma's role in the continuity of care

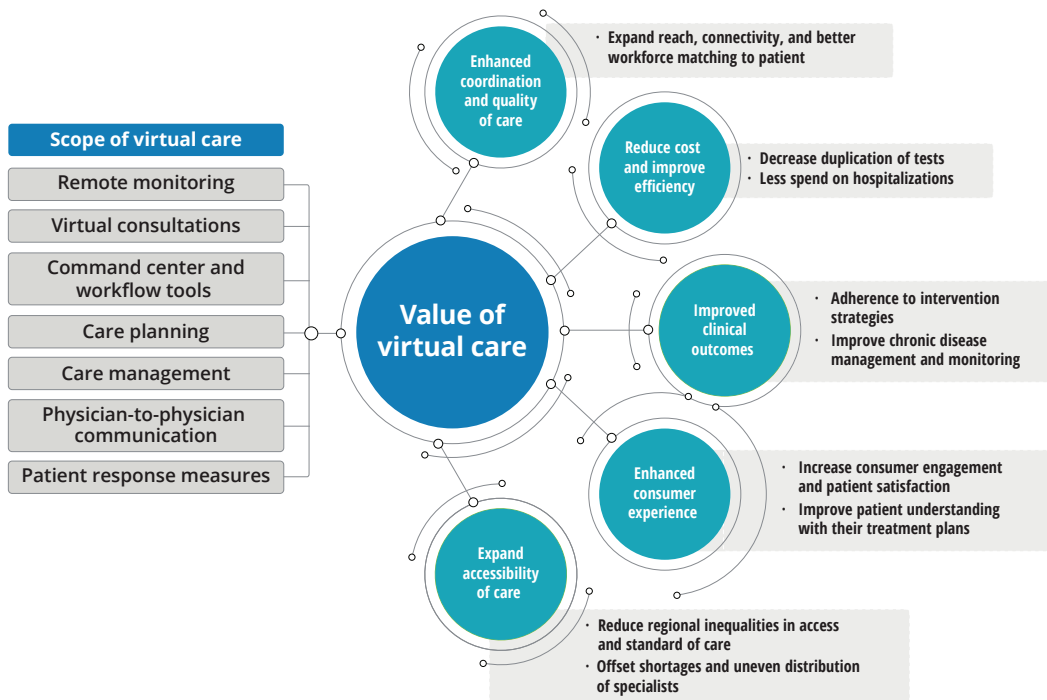
In 2020, as a result of the pandemic, the number of virtual visits soared. For example, in April 2020, according to CVS, virtual visits made up nearly 70% of all patient provider interactions in the United States. Some estimate over US\$30 billion of medical services were delivered virtually in 2020.⁴¹

These trends in virtual health uptake unfolded similarly across the world.⁴²

Virtual health enables sharing of data and insights across the complete circle of care—from disease prevention to treatment and ongoing monitoring.⁴³ Virtual care is a source of real value (figure 1), and as pharma companies engage with these platforms, they can improve continuity of care and cost-effectiveness.⁴⁴

FIGURE 1

The value of virtual care



Source: Deloitte, *Virtual care is here to stay*, 2020.

The shift in health care delivery—from an office-centered, episodic visit model to a real-time, trigger-and-response model—is likely to provide a better understanding of the role and effectiveness of pharmacology in treatment. Prescriptions, fill rates, lapses, and switches are expected to have a new pace and cadence adjusting to this new reality.⁴⁵ Coupled with other digital health tools, virtual care may fundamentally change health care access and deliver an improved care experience.⁴⁶ Virtual health has the capacity to inform, personalize, accelerate, and augment prevention and care.⁴⁷

MAXIMIZING NEW CARE PATHWAYS

Many doctors and patients shed their discomfort with video visits⁴⁸ as use of telemedicine and remote monitoring skyrocketed during the pandemic.⁴⁹ This may also be a plus for virtual interactions with pharma sales representatives and medical liaisons as the online experience becomes the *digital front door* for health systems.⁵⁰

Going forward, health systems are expected to continue making investments⁵¹ and a hybrid model of virtual and in-person visits will likely be the norm postpandemic.⁵² Pharma companies have an opportunity to help improve online visits and help

health care professionals (HCPs) understand the benefits of these new care pathways.⁵³

SUPPORTING CLINICAL LEADERS AND PHYSICIANS IN IMPROVING VIRTUAL HEALTH

According to a survey of clinical leaders by the Deloitte US Center for Health Solutions, continued investment into virtual health is a strategic imperative. However, the majority of those leaders (almost 75%) say they *do not currently track*, or only partially track, quality measures for virtual health. These quality measures—such as medication adherence and continuity of care—are critical to pharmaceutical companies and for building data on health improvement and outcomes (figure 2).⁵⁴

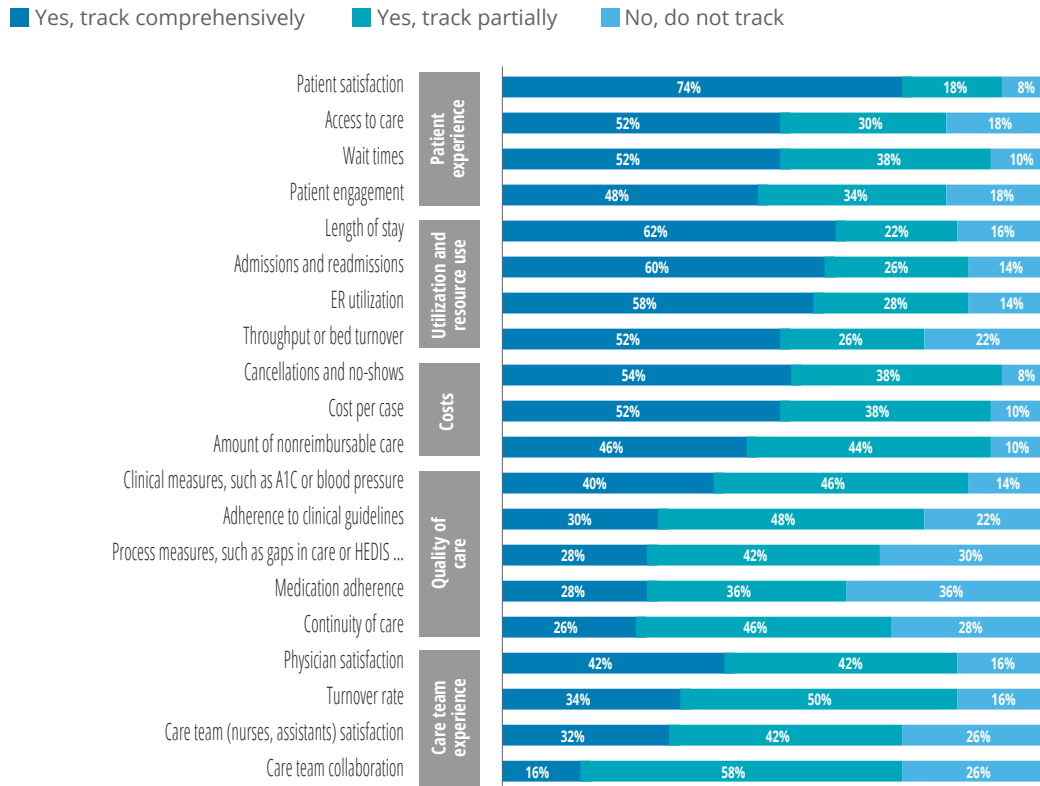
Only 36% of these leaders say they provide “web-side manner” training for communicating and interacting with patients remotely—training that most physicians report they would like to have.⁵⁵ Learning how to empathize virtually should help clinicians build greater trust—the trust necessary for helping patients follow treatment plans.⁵⁶ Pharma companies could help clinical leaders address this need by becoming partners in virtual health training.



FIGURE 2

Metrics to measure performance of virtual health programs

Survey question: Which of the following do you use to measure performance of your virtual health program?



Source: Bill Fera, MD, et al., Virtual health accelerated, Deloitte Insights, 21 February 2021.

Policymaking: Reimbursement and regulations for virtual health uptake

Eased regulations during the pandemic increased adoption of telemedicine in many countries, but reimbursement and regulatory policies postpandemic will be key to permanent uptake and growth.⁵⁷ Eased regulations are likely to stay in early adopter

markets such as the United States,⁵⁸ Canada,⁵⁹ China, and Singapore,⁶⁰ but more work needs to be done in many other countries. Going into COVID-19, many countries had to work across reimbursement, policy, and regulatory to enable scaled adoption of telemedicine (figure 3).⁶¹ Biopharma and medtech companies may want to keep abreast of this trend in order to shape their interactions with health care providers locally.

FIGURE 3

The policy, regulatory, and financial environment surrounding the use of telemedicine

Country	Has national legislation, strategy, or policy on the use of telemedicine?	What is the main source of funding for eHealth?	Defines jurisdiction, liability, or reimbursement of eHealth services (e.g., telehealth)?
Argentina	Yes	Public	No
Australia	Yes	Public	Yes
Austria			
Belgium	Yes	Public	No
Canada	Yes	Public	Yes
France	Yes	-	-
Germany	Yes	-	-
Ireland	Yes	Public	Yes
Israel	Yes	Public	Yes
Italy	Yes	Public	Yes
Japan	Yes ²	-	Yes
Mexico	Yes ¹	Public	No
Netherlands	Yes ¹	Public	Yes
Portugal	Yes	Public	Yes
Spain	No ¹	Public	No
Switzerland	No	Public and private	Yes
United Kingdom	Yes	Public	No
United States	Yes ¹	-	Yes

Notes: ¹ no specific legislation on telemedicine but use is allowed, ² use of telemedicine is allowed but with restrictions. Private funding includes private or commercial funding and public-private partnerships.
Source: OECD, *Health working paper no. 116*, January 2020.

Follower markets such as Japan and Indonesia may catch up with early adopters with government support. India received much-needed government clarity regarding telemedicine, resulting in a slew of telemedicine platforms and startups.⁶² Conservative markets such as Hong Kong and South Korea saw some uptake during the pandemic, but are unlikely to see lasting adoption without high demand or clear unmet need.⁶³

In the United States, policies established by Medicare and most private insurers for COVID-19 enabled providers to receive the same rate for telehealth visits as office visits. Providers incurred significant costs to ramp up technology, but once “up to scale,” experts say a fee restructuring is likely.⁶⁴ Reimbursement and payment parity will be a leading concern for physicians over the next year, influencing future use.⁶⁵ US regulators also plan to audit telehealth services for home health care agencies and nonproviders that were authorized during the pandemic to assess policies for future reimbursement and for potential fraud.⁶⁶



Going forward in the United States, Medicare policies regarding telehealth reimbursement will certainly influence pace of uptake and its role in patients’ care. Specific details for telecare reimbursement will need to be further clarified (i.e., new patient consults vs. only established patients, length of time spent on data gathering vs. observation, etc.). Time spent analyzing health data from one vs. multiple devices will shape physician uptake, and thus, shape biopharma and medtech’s future opportunities to enhance physician and patient experience and outcomes with telehealth.⁶⁷

Deloitte expects virtual video visits to doctors will rise to 5% globally in 2021, up from an estimated

1% in 2019.⁶⁸ The Organization for Economic Co-operation and Development (OECD) reports that 8.7 billion physician visits, worth a total of approximately US\$500 billion, took place in 36 countries in 2019 (figure 4).⁶⁹ Just 5% of visits being virtual would translate into more than 400 million video visits and about US\$25 billion in value, depending on how much doctors are paid compared to in-person visits.⁷⁰

FIGURE 4

Total number of annual doctor’s visits by country, 2019 or latest available data

 Country	 Annual visits (millions)
▶ Japan	1,594
▶ United States	930
▶ South Korea	866
▶ Germany	829
▶ Turkey	801
▶ Italy	411
▶ France	385
▶ Mexico	361
▶ Spain	341
▶ United Kingdom	340
▶ Lithuania	27
▶ Ireland	25
▶ Finland	24
▶ Norway	24
▶ Denmark	22
▶ New Zealand	18
▶ Slovenia	14
▶ Latvia	11
▶ Estonia	7
▶ Luxembourg	4

Sources: Deloitte analysis; OECD.

TELEMEDICINE'S POTENTIAL FOR THE WORLD'S MOST VULNERABLE



The best and most advanced technologies are useless for those without access to the internet or technology.⁷¹ Half of the world's population does not have access to medical services because they are either inaccessible, unavailable, unaffordable, or of poor quality.⁷²

The World Telehealth Initiative (WTI) is a nonprofit serving patients in need globally with a network of volunteer health care professionals. WTI partners with Teledoc Health for state-of-the-art technology to deliver essential medical services virtually—despite specialists and patients being countries apart.

Malawi is one of the poorest countries in East Africa, with only one doctor for every 62,500 people (figure 5).⁷³ Now, a doctor at the Baylor College of Medicine in Texas is assisting surgeons and physicians in Malawi with complicated fistula procedures. Telemedicine has great potential in sub-Saharan Africa and rural areas where doctor-to-patient ratios are severely handicapped.⁷⁴

FIGURE 5

Approximate doctor-to-patient ratios in various countries

 Country	 Doctor ratio
▶ Australia	1:285
▶ United Kingdom	1:360
▶ United States	1:400
▶ Italy	1:583
▶ Ghana	1:1,000
▶ India	1:1,511
▶ Nigeria	1:3,500
▶ Malawi	1:62,500

Note: Data collected from 2017 to 2020.
Source: Deloitte analysis.

Policymaking: Funding larger digital health initiatives

Telemedicine and virtual care are part of larger digital health initiatives receiving funding. Corporate funding for digital health reached a record US\$21.6 billion globally in 2020—an increase of 103% over 2019.⁷⁵ Governments are committing to funding new digital health

innovation and more health care spending in the next year:

- AUS\$2.4 billion in Australia⁷⁶
- CAN\$240 million in Canada⁷⁷

INR₹2.2 trillion (US\$30.1 billion) in India (doubling health care spending)

In China, 2021 is expected to be a year of policy-oriented e-medicine development and health care reform. Government policies around the world will play an important role in furthering development of the consumer health market.⁷⁸

New point of care: Tech giants bring clinical care to the home

The home is becoming the hub of connected living. Amazon Care, along with Intermountain Healthcare and Ascension, are founding members of *Moving Health Home*, a new health care coalition to designate and expand the home as a site of connected clinical service.⁷⁹ Amazon Care is currently a benefit for Amazon employees in Washington,⁸⁰ offering a virtual-first medical platform, mobile care, and prescription delivery,⁸¹ but plans include expanding to health plans and other employers.⁸²

As clinical trials move to the home or become virtual, smartphones and wearable technologies are becoming important clinical tools.⁸³ Apple⁸⁴ is boosting the number of health-related features accessible on its Watch to facilitate its use in medical research.⁸⁵

THE VIRTUAL CARE CLOUD

Cloud computing is the heart of digital transformation. Amazon, Google, and Microsoft have all developed offerings for the health care cloud market seeking to transform patient care. New virtual care capabilities, remote monitoring, and patient care coordination are now part of cloud offerings by Microsoft Cloud for Healthcare service.⁸⁶ Google Cloud also provides services for virtual health care and helped Mayo Clinic move to the cloud. Google recently opened an office next door to the clinic in Rochester, Minnesota.⁸⁷ The idea is for Google engineers to work alongside Mayo Clinic researchers and apply advanced computing techniques and AI to health care problems.⁸⁸

New point of care: Digital pharmacies

EXPLOSION IN HOME DELIVERY

Demand for pharmacy home delivery surged during the pandemic, from local and major drug retailers to government providers.⁸⁹ In the United Kingdom, the National Health Service (NHS) has instituted free prescription delivery home delivery services to patients registered with a GP in England.⁹⁰ Amazon launched Prime Pharmacy at the end of 2020,⁹¹ and also acquired online pharmacy PillPack in 2019.⁹²

Amazon's steps aren't solely about adding prescription drugs to its ever expanding list of services. They are a telltale sign that Amazon's continuing long-term strategy is to collect and use data for a more complete picture of consumer behavior—in the hope of creating a better consumer experience and the underlying platform which drives it.⁹³

COVID-19 was a tipping point motivating many entrepreneurs to launch disruptive health care delivery businesses in 2020.⁹⁴ Digital pharmacy startups, inspired by the success of Amazon, are zeroing in on underserved or niche populations.⁹⁵ In Washington D.C., CaryRx rose to meet the needs of its under-resourced communities with free, same-day prescription deliveries.⁹⁶ The digital pharmacy is taking steps to become a full-stack pharmacy—building a new technology platform, partnering with health plans and pharmaceutical companies, expanding services, and breaking into new markets.⁹⁷

DRONE DELIVERY GROWS DURING THE PANDEMIC

Several companies now have certification from the US Federal Aviation Administration for drone delivery—Amazon, Google, and Google's subsidiary, Wing.⁹⁸ Wing and Walgreens prescription drone delivery service in Christiansburg, Virginia, saw a 500% increase in business during the pandemic. They say drone delivery is here to stay.⁹⁹ Others are

also using drone delivery for prescriptions as well as medical supplies.¹⁰⁰ The NHS launched the United Kingdom's first COVID-19 test drone delivery service in Scotland utilizing advanced air mobility company Skyports.¹⁰¹ COVID-19 tests are also being delivered via drone by Zipline in Africa.¹⁰²

DIGITAL PHARMACIES EXPANDING INTO TELEMEDICINE

Some digital pharmacies are expanding into other services, such as telemedicine.¹⁰³ Around the world, a large number of online pharmacies are not regulated. The European Alliance for Access to Safe Medicines (EAASM) found that 62% of medicines bought online were either substandard or counterfeit.¹⁰⁴ As digital pharmacies expand services to telemedicine, the EAASM warns that some online pharmacies are unlicensed and offering "online consultations" in order to appear credible.¹⁰⁵

New point of care: Retail pharmacies create health care supercenters

Retail pharmacies are growing to provide greater levels of health care services. In 2020, Walmart launched retail adjacent/embedded health care supercenters—that incorporate primary care physicians—and immediately hit capacity.¹⁰⁶ Walgreens' digital health marketplace now has 15 new or expanded national and local providers offering cancer screening, diabetes management, vision, and mental health services to address comprehensive care during the pandemic.¹⁰⁷

In today's health care ecosystem, the pharmacist is a trusted, critical, and—often—underutilized resource. With the help of automation and AI algorithms, the future pharmacist may be a

recognized care provider, prescribing acute medications and managing chronic diseases.¹⁰⁸

PHARMACY AS VACCINE HUB

While pharmacies have always been among the most frequent health care touchpoints for patients, the pandemic has elevated the role of the pharmacist and spawned further pharmacy care delivery capability.¹⁰⁹ Pharmacy vaccinations have been a growing trend, lowering costs and making immunizations more convenient.¹¹⁰ The United States fueled this trend by enlisting Walmart, Walgreens, and CVS Pharmacy to provide COVID-19 vaccinations for millions of people at an estimated 40,000 stores throughout the country.¹¹¹ Pharmacies are also providing vaccines offsite. A small Pennsylvania pharmacy, Skippack Pharmacy, helped its county achieve one of the highest per capita vaccination rates in the state.¹¹²

Pharmacies owned by Albertsons are making vaccine information available through Google's Business Messages. Using Google Search and Google Maps, users can quickly and accurately get information for where, when, and how they can get the vaccine at Albertsons' pharmacies.¹¹³

POINT-OF-CARE TESTING INNOVATION, DIAGNOSTIC ALGORITHMS ENABLE EFFICIENCY AND MOBILITY

The World Health Organization (WHO) endorsed point-of-care testing (POCT) as a top research priority in response to COVID-19. POCT platforms using smartphones for respiratory and metabolic diseases are transforming care in the new era of 5G, Internet of Things (IoT), AI/machine learning, and alternate care sites.¹¹⁴ POCT may also improve workflow efficiency, reducing the steps necessary to get a diagnosis.¹¹⁵ POCT for COVID-19, like Roche's SARS-CoV-2 Rapid Antigen Test, is designed for resource-limited settings with results expected in 15 minutes.¹¹⁶

INCREASING ACCESS TO COVID-19 TESTING IN AFRICA

UK startup Mologic is developing lateral flow and rapid diagnostic testing technologies. In April 2021, Mologic was selected for the US National Institutes of Health's (NIH) RADx initiative. Through RADx, Mologic will receive technical expertise for product development and validation, regulatory guidance to help meet criteria for FDA authorizations and support to help the company scale up the manufacturing of COVID-19 tests in the US.

Mologic will be also be making the unique self-test design available to their global customers and partners through their contract research and manufacturing program. In low- and middle-income countries, the test will be manufactured and made available by Global Access Diagnostics (GAD), at cost of production and distributed through commercialization partners. Mologic recently set up a new manufacturing facility in Senegal.¹¹⁷

Data-driven opportunities for medtech, growing competition from consumer tech

As interest in virtual care, home care, and remote monitoring services grow, so will medtech's competition from consumer technology companies.¹¹⁸ Investments should be made that:

- Improve remote access to patients
- Enable the transition to more care outside of the hospital
- Shift the emphasis toward prevention and well-being¹¹⁹

CONSUMER DEVICES ADAPTING TO THE HEALTH CARE NEEDS OF THE ELDERLY

More older people are coming online, and consumer devices are being adapted for the elderly.¹²⁰ Louder smartphones and voice-activated IoT devices are being used to improve the quality of life for the growing elderly population in China.¹²¹

Multipurpose devices are merging health care with consumer electronics. CVS Health Symphony is a mesh network of sensors from in-home and wearable devices that detects falls, monitors motion, oversees room temperature and air quality, and provides an emergency alert service when needed.¹²²

The elderly at home can benefit from real-time monitoring devices that track physiological as well as psychological status. The iCardioGuard measures heart rate, blood pressure, and vascular parameters, in addition to stress and fatigue.¹²³

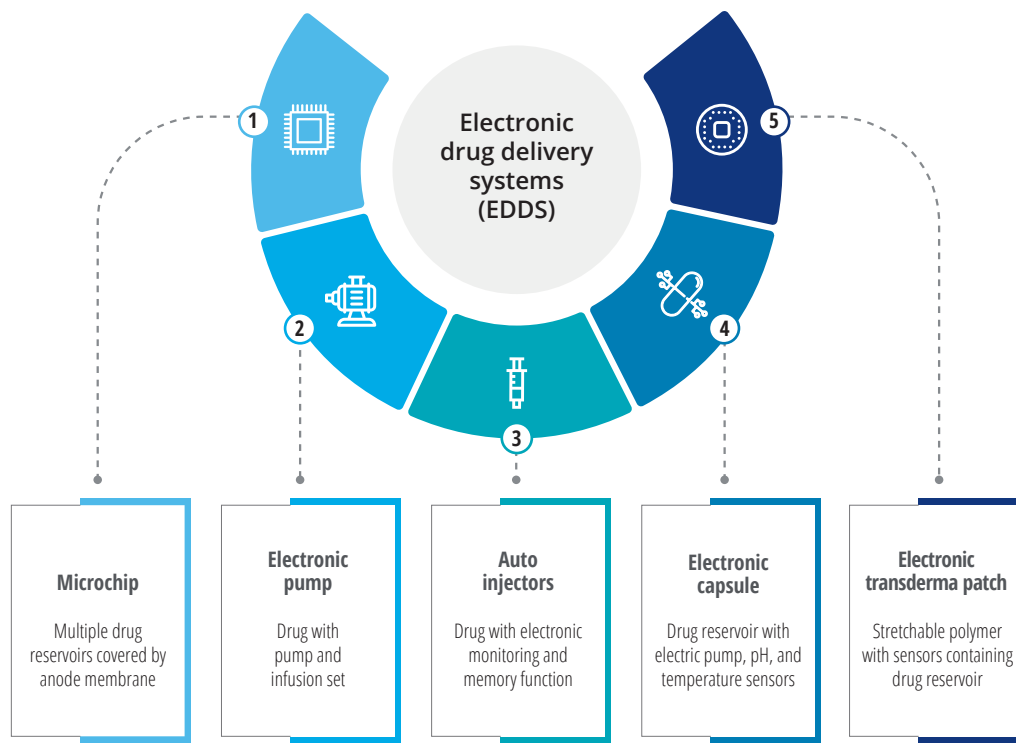
DATA DRIVES INNOVATION FOR DRUG DELIVERY DEVICES

Empowering patients to take control of their own health through the use of devices, data, and other insights is a critical piece of health care delivery.¹²⁴ Electronic drug delivery systems are smart devices that enable medicines to be seamlessly delivered to patients and may be remotely monitored (figure 6).¹²⁵

In addition to controlled dosing and better adherence, these digitally connected devices offer potential health savings.¹²⁶ The utilization of drug delivery systems is expected to grow due to both an increase in virtual care and an increase in the number of the elderly with chronic disease.¹²⁷

FIGURE 6

Electronic drug delivery systems



Source: *Journal of Drug Delivery Science and Technology*.

Transdermal drug delivery can be a solution for elderly patients who have trouble swallowing pills. Transdermal patches adhere to a patient's skin and deliver a drug over time, often over several days. The patient doesn't have to remember to take their medication, and automatic dosing is a boon for caregivers.¹²⁸

Innovation in data-driven solutions are driving the growth of drug delivery devices.¹²⁹ Timely and appropriate insulin dosing is a key concern for diabetes patients,¹³⁰ and connected insulin pens are not new.¹³¹ However, new ways to collect and share data are driving a new generation of smart insulin pens. Eli Lilly is currently collaborating with WellDoc's digital health platform and BlueStar

diabetes management solution, for Eli Lilly's new connected insulin pen.¹³²

Smartphone-connected pacemakers are one of the Cleveland Clinic's top innovations for 2021. Remote monitoring of pacemakers is an essential part of care, and traditionally, takes place through a bedside console that transmits data to the physician at specified intervals. While millions of patients have pacemakers and defibrillators, adherence to remote monitoring has been suboptimal. Used in conjunction with a mobile app, connected pacemakers can seamlessly transmit data to a physician while giving patients greater insight into their health data.¹³³

Rethink care delivery and new points of care:

- How is telemedicine evolving for patients and physicians? As uptake grows, how can we address physician and patient pain points with telemedicine as part of the patient journey?
- How are health equity needs being met as telemedicine grows and virtual interactions become part of the patient journey?
- As virtual care takes a more dominant position in care delivery, how are patient education and physician education needs different? How can we better support physicians for virtual patient interactions and in training for “web-side manner”?
- How are we assessing quality in virtual care? Is virtual care supporting adherence?
- As the home becomes a clinical care site, what opportunities and/or requirements arise for life sciences companies?
- With remote testing and vaccination capacity built up to address the pandemic, what health care enhancement opportunities arise to take advantage of that capacity, infrastructure, and increasing consumer comfort with remote care? Are we working effectively enough with pharmacists given their increasing role in care delivery?
- As technology giants address data interoperability challenges and amass more comprehensive consumer data, what are the opportunities to partner and gain additional insights?
- Are we missing any new potential partners in consumer health tech?



New customer-centric commercial model: Meeting physicians where they are, on their terms, and through more meaningful interactions

Shift to digital and virtual, personalization and empathy

Even before the pandemic, the threat to the pharma commercial model was already real.¹³⁴ At the start of the pandemic, digital enablement became a necessity, with shifts to completely virtual models almost overnight. Now the transformation is underway. The commercial model shift will have digital and virtual engagement at its core, not personal promotion.

Personal promotion will increasingly be designed to augment virtual engagement vs. the inverse, requiring more meaningful and practical content and more compassion for all the HCPs face. New relationships can be deepened by content that resonates with individual HCP needs and actions that demonstrate compassion and empathy. Life sciences companies should meet physicians on their terms, where they are, and have content available on demand.

As they seek greater value in interactions, physicians are requesting:

- Digital patient education
- Education on remote patient care
- Information to help patients access labs, tests, and imaging¹³⁵

Remote selling soars, but one size does not fit all

When hospitals and doctors' offices barred in-person sales visits to minimize virus spread, virtual visits with sales reps soared. Companies sent about 7 million emails and conducted more than 316,900 remote meetings with doctors globally in April 2020. In January 2020, 1.2 million emails were sent and 4,900 remote meetings conducted.¹³⁶

Almost overnight, doctors adopted virtual platforms out of necessity.¹³⁷ Today, some doctors say they will stick to video calls with reps, but others miss in-person visits. A hybrid, more supportive, commercial model is evolving that is a mix of both.¹³⁸

CULTURAL DIFFERENCES WILL DETERMINE FUTURE INTERACTIONS

There have always been cultural differences between markets in the relationship between a sales representative and physician. For example, many physicians in Germany are expected to go back to face-to-face visits, but in countries such as Spain, less than half are expected to go back.¹³⁹

MEDICAL SCIENCE IS KING

Experts say reps who understand the science, who are interested in patients, and who are capable of having meaningful discussions with HCPs will still be needed. This is especially true for medtech products that depend on device servicing and on-call technical support.¹⁴⁰

Physicians really want to understand therapeutics. Perhaps the more on-demand potential of virtual visits created greater opportunity for more meaningful interactions when they did occur. During the pandemic, some pharma representatives report having 30-minute conversations with HCPs, compared to maybe five minutes prepandemic.¹⁴¹

One of the unfortunate results from COVID-19 was the decline in screening and earlier diagnoses of diseases.¹⁴² While these rates of screening and diagnosis are increasing to near prepandemic levels, there is an important role for medical

organizations of life sciences companies to increase their focus on appropriately shaping care—from broader access, to the right and timely screening and detection approaches, to earlier and appropriate treatments for patients. Medical representatives can have a more comprehensive, system-wide view of specific disease patient journeys; thus knowing where in a given geography and health care system community, the key focus areas should be to advance better patient access and outcomes.

Driving value through digital channels on demand

During the pandemic, some companies delayed new launches because of the education required for launching new products.¹⁴³ Others explored new channels such as advertising on telemedicine websites.¹⁴⁴ Many companies observed and reacted to the increasing heterogeneity in local market outbreaks, legislation, remote care and technology adoption, and health care capacity. These increasing differences will require flexibility in future approaches and commercial models.

The post-COVID-19 opportunity is for the industry to rethink how to engage with physicians and how to drive value through digital channels and products on demand. How companies segment their customers must evolve to address regional differences as well as to understand how HCPs' interactions across channels drive behavior change. Representatives should be able to seamlessly leverage in-person, remote, and digital channels to meet the physician where they are as well as learn from each touchpoint to inform future engagements.

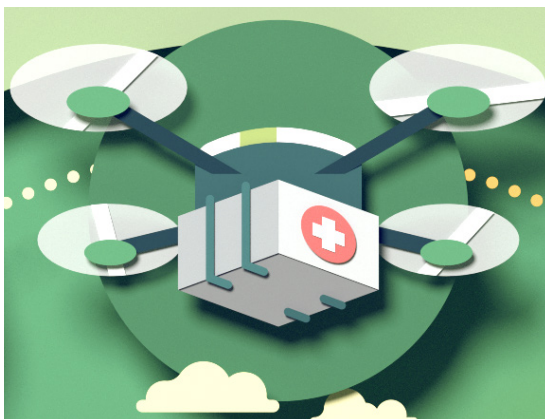
EMERGING CHANNELS

According to a recent survey of pharma/health care marketers, during the pandemic, spending was raised on every digital option: video, mobile, machine learning, AI, analytics, marketing research, automation, paid digital, and websites.¹⁴⁵ In the year ahead, respondents expect social media to be the most important emerging channel, followed by patient engagement, and the growth of consumerism in health care.¹⁴⁶

DIGITAL AND VIRTUAL INTERACTIONS REQUIRE NEW SKILLS

As the use of digital technologies rises,¹⁴⁷ pharma company representatives may benefit from additional coaching to become more compassionate and empathetic to HCP needs, as they too are often overwhelmed with the pace of change and the pandemic's all-encompassing implications for them and their practice. Care delivery has fundamentally changed, and HCPs are rapidly adjusting.

Creating meaningful interactions requires a different approach, and conveying empathy in remote interactions is a new skill. Empathetic exchanges involve actively listening and digging a little deeper to gain HCP perspective.¹⁴⁸



More investment for medical affairs

Education is a key focus of medical affairs (MA) teams and the shift from sales to medical affairs has been advancing.¹⁴⁹ Sales forces are being downsized.¹⁵⁰ The pandemic amplified MA's importance in driving engagement and providing personalized, educational value.¹⁵¹ Medical science liaisons are becoming a key communication channel between manufacturers and physicians, particularly with the expansion of novel therapies.¹⁵² In the next year, medical affairs will see more investment and more comprehensive, strategic partners to complement its expanding roles and responsibilities.¹⁵³

The new medical conference model is hybrid and social

As physicians look for more scientific support, the trend is to deliver the right content, on demand, at a time convenient for the physician—including less travel.¹⁵⁴ The mega medical congresses of the past are expected to make way for more virtual, focused, and hybrid physical/digital events.¹⁵⁵ The new medical congress¹⁵⁶ will see growth in technologies such as AI, chatbots, virtual rooms, and learning platforms.¹⁵⁷

Luca Dezzani, vice president of US medical affairs in oncology at Eisai, sees social media augmenting congresses and enhancing networking. “At the 2020 ASCO conference, I was following on two separate screens—one was the program, the other was my Twitter feed because there was so much discussion happening there.”¹⁵⁸ Companies see the need to address shifting market dynamics and becoming comfortable with new ways of engagement.¹⁵⁹

Rethink the commercial model:

- *How are we understanding and meeting the individual physician's preferences in interactions? Are we creating personalized, meaningful, and empathetic interactions?*
- *Are we developing the content physicians want and making it available on demand?*
- *What type of training will representatives need to better engage with HCPs remotely and empathetically?*
- *What investments are we making for the changing role of medical affairs?*
- *What new opportunities does a hybrid medical conference model present?*
- *How can learnings from this past year act as a catalyst to deliver a truly omnichannel experience for physicians?*
- *How are portfolio decisions driving different medical affairs operation models?*



New types of collaborations and clinical trials reshaping research and development

Creating new efficiencies, shortening development timelines

Accelerated digital transformation during the pandemic saw agile teams, speed to market, release of the minimum viable product, and senior management aligned with the process changes required for increased speed to market. An industry poll in Q1 2021 showed that more than one-third of participants believe COVID-19 accelerated digital transformation of the pharma industry by five or more years,¹⁶⁰ making predictions for the Future of Health™ now a reality.¹⁶¹

The rapid development of novel vaccines for COVID-19 demonstrates that a new type of streamlining and efficiency is indeed possible. Two novel COVID-19 vaccines were developed, tested, and authorized in less than a year, compared to an industry mean average of 8.2 years for new drug development and review.¹⁶²

The pandemic exposed long-standing inefficiencies within biopharma operating models.¹⁶³ But orthodoxies have been broken, and there is greater commitment and confidence to shift new drug development timelines down. Companies are reassessing processes and challenging steps previously thought to be necessary and fundamental.

Biopharma companies are adopting various strategies for innovating clinical trials to shorten timelines, including new trial designs and new technologies such as AI. Using AI, industry can use data from previous trials, including failed ones, to improve future designs.¹⁶⁴

With clarity of purpose and new collaborations (always thought possible, but finally executed), life science companies are setting new precedents for how quickly a new products can be brought to market. The future of the industry should not be stymied by big and expensive launches, steering committees, and cumbersome processes—or solutions may be outdated before they even reach the market.¹⁶⁵

RACE TO SUPPLY THE WORLD WITH VACCINES

Amid vaccine shortages in certain parts of the world, China's Sinopharm hopes to expand access for its vaccine through more cross-border collaboration. The pandemic may be the company's best chance in decades of breaking into the global market. Sinopharm says it has the capacity to produce 1 billion doses of its vaccine by the end of the year. Hungary was the first EU nation to start using the vaccine¹⁶⁶ as well as Zimbabwe in Africa.¹⁶⁷

As Sinopharm makes small inroads into the global market, expansion is most likely in Africa and Asia.¹⁶⁸ If Sinopharm is successful in meeting some of the global vaccine demand beyond China's borders, it will accelerate confidence in China's R&D capability, which will have long-term, positive implications for the industry.

Innovative partnerships accelerating development

New partnerships for biopharma and medtech companies are evolving that were not seen even 18 months ago. Companies are seeing value beyond their typical silos and moving beyond traditional pharma/biotech partnerships to medical device/biotech/pharma/health care partnerships.

“I believe that the collaboration the pandemic spurred will not only open up new areas of collaboration that will live on, but that it will also be looked back on as one of the many great success stories of the COVID-19 response.”

— Vas Narasimhan, CEO, Novartis¹⁶⁹

New collaborations with academia, biotech, platform companies, and data providers were already happening before COVID-19, but the pandemic accelerated time, attention, and capital to these types of collaborations by the sector. This is expected to be the new normal by many stakeholders, including regulators. Public-private partnerships are also on the rise with more collaboration between governments, research institutions, and the private sector. Industry cooperation, which includes universities and other unaffiliated organizations, is a great win for public trust.¹⁷⁰

COVID-19 research will continue to require partnerships with innovative contract research organizations (CROs) as pandemic trials are a long-term opportunity.¹⁷¹ As strategic partners, CROs can provide access to specialized expertise and a wide range of potential trial participants.¹⁷²

Companies that typically choose from a small list of outsourcing vendors are expanding their view and looking for different capabilities—those better suited for their specific trial and environment.¹⁷³

Media attention for platform technologies will drive more time, attention, and capital from larger

players toward innovative, emerging platform technologies such as mRNA,¹⁷⁴ not just for viruses and vaccines, but also rare disease, oncology, and infectious diseases.¹⁷⁵

Many adaptations made to trials during the pandemic are informing oncology trial transformation for the future.¹⁷⁶ Strategic partnerships can lead to higher quality real-world data (RWD),¹⁷⁷ and oncology innovation will continue to depend on leveraging partnerships, including those with nonprofit patient advocacy groups, academic research centers, and technology companies.¹⁷⁸

Beyond vaccines, oncology is expected to continue to be a major driver of the sector's topline growth in 2021 (figure 7). Oncology accounts for six out of the 10 biggest new sales generators and four of the top 10 bestselling products.¹⁷⁹ According to Evaluate, sales of COVID-19 vaccines though are expected to reach US\$10 billion to US\$15 billion in 2021, with the Pfizer/BioNTech vaccine forecast to be the top seller. Evaluate predicts that Moderna's COVID-19 vaccine will be the market leader by 2026.¹⁸⁰

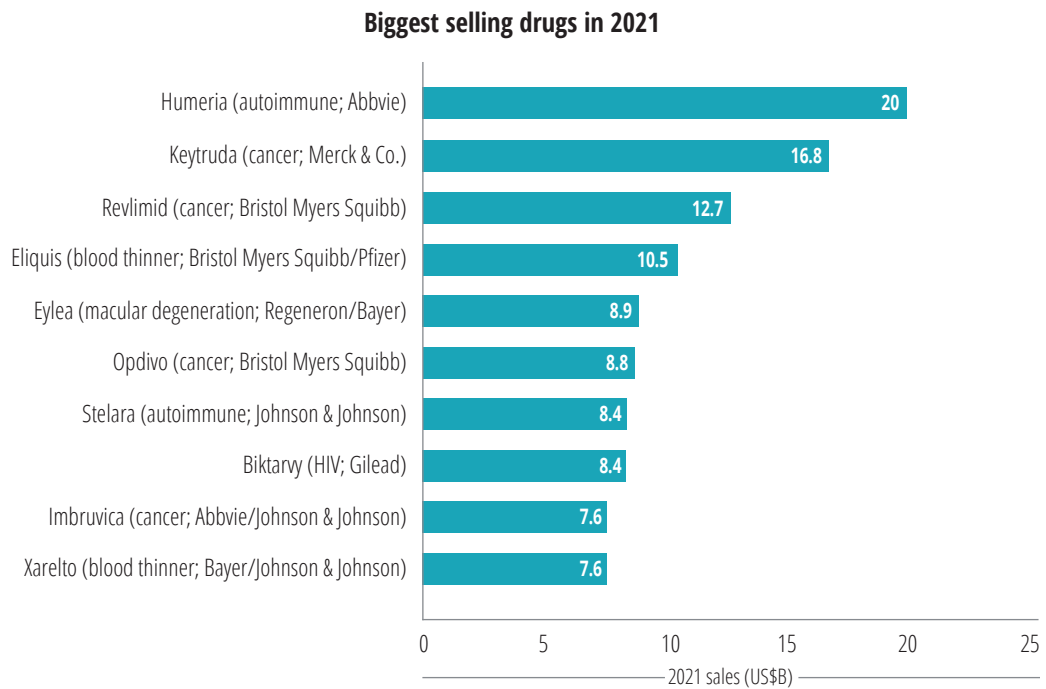
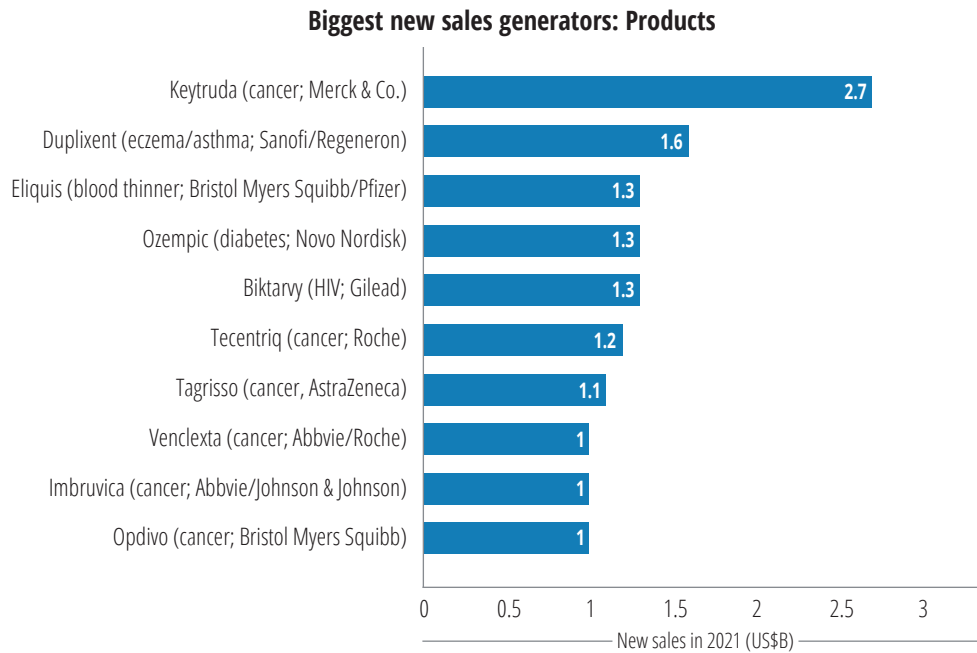
Despite the acceleration of interest and investments in vaccines, antibiotics research is still in need of research funding and partners. A silver lining to the pandemic is that it spurred medical students' interest in infectious disease. Experts see a long-term increase in science, medicine, and pandemic-related research. At Tel Aviv University, registration for undergraduate studies in life sciences and biomedical sciences almost doubled in the past year.¹⁸¹

Collaborations with big tech will continue to grow with new opportunities to experiment with quantum computers, offered through cloud computing interfaces from established companies as well as startups.¹⁸²

FIGURE 7

Drugs driving biopharma's topline growth for 2021

■ 2021 sales (US\$B) ■ New sales in 2021 (US\$B)



Note: Excludes COVID-19 products.
Source: EvaluatePharma.

PARTNERING FOR QUANTUM COMPUTING CAPABILITY

Boehringer Ingelheim is the first pharmaceutical company worldwide to join forces with Google in quantum computing. Quantum computing offers the potential to significantly accelerate and optimize the discovery of future new medicines for patients. The Boehringer Ingelheim/Google partnership is designed for three years and is co-led by the newly established Quantum Lab.¹⁸³

Deloitte research shows that companies should prepare to participate in an emerging ecosystem where disease foundations, patient advocacy groups, health plans, health systems and physicians, regulators, competitors, tech companies, and wellness organizations are all better connected—with the patient at the center.¹⁸⁴

New trial designs enable more patient involvement and diversity

Pandemic trials have proven that big studies need not necessarily be multiyear affairs.¹⁸⁵ Regulators are becoming more flexible about clinical trial design and the speed of trials. Health care is bringing novel data streams into protocol design, and more data collected remotely will reduce the need for physical visits.

Virtual trials and remote monitoring enable greater patient involvement and give patients an active voice in research. Patients can be recruited globally, and participants do not have to be in a central geographic region, while research staff is typically in one centralized group. Broadening eligibility criteria and adopting more inclusive enrollment practices should promote diversity and improve

the quality of studies. A study population needs to be representative of the population that may ultimately use a drug.

More on diversity and health equity is discussed in the section for “Advancing humanity: Environment, social, and governance (ESG) imperatives” of this report.

“We recognize that achieving clinical trials that include diverse populations presents an ongoing challenge.”

— PhRMA¹⁸⁶

Potential ways to improve clinical trial diversity:

- Assess trial design and identify more opportunities for hybrid or decentralized trials
- Identify and recruit trusted sources in the community to promote trials to specific, diverse populations
- Reduce the burden of frequent visits to specific sites and consider flexibility in visit windows, if possible
- Use electronic communications to replace visits and provide investigators with information, such as phone, email, and social media platforms
- Use digital health technology tools that can provide real-time data
- Provide transportation
- Address schedule conflicts with caregivers or family members that can be a barrier to participation¹⁸⁷

MORE CONVENIENT DECENTRALIZED TRIALS BRING NEW INSIGHTS

Decentralized clinical trials are executed at the point of care through telemedicine and mobile and local health care providers.¹⁸⁸ At the US Food & Drug Administration (US FDA), “decentralized trials” refer to the decentralization of technologies.¹⁸⁹ With support from regulatory bodies, there is a trend toward more decentralized, patient-centric trials in the long term, and they offer many advantages (figure 8).¹⁹⁰

Through the use of smartphones, wearable technologies, and remote monitoring, decentralized trials facilitate new sources of data and bring new insights, which may facilitate better research.¹⁹¹ Consumer-facing products are forging partnerships with payers, health systems, and clinical researchers.¹⁹² Participants are increasingly

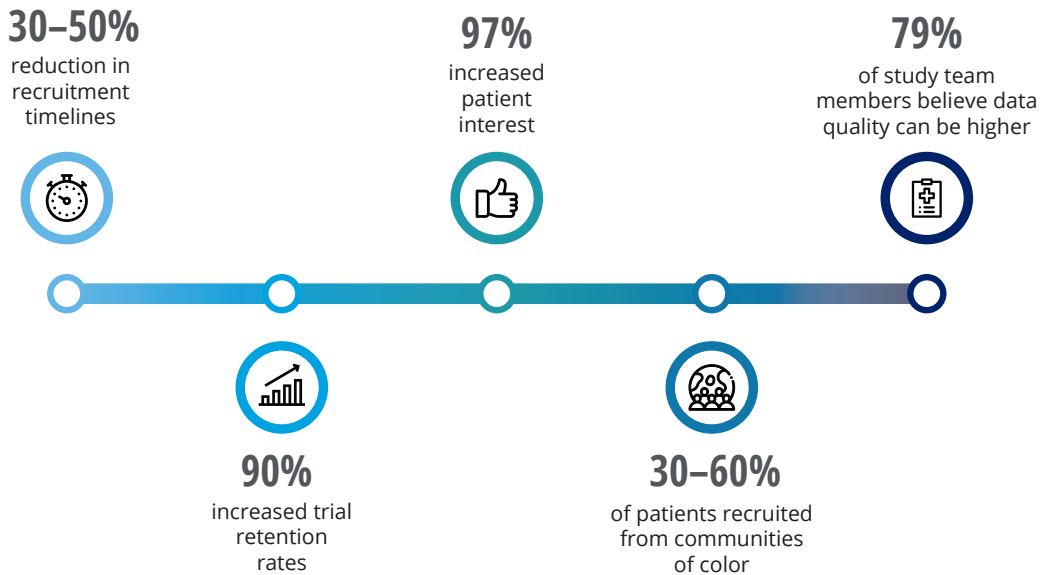
receptive, since they can remain at home, and trials are not tied to a physical location. However, principal investigators are still getting comfortable.¹⁹³

Like the virtual transformation of the commercial model, clinical trials also had to keep pace with, if not transform overnight, to determine how some and/or all of a trial could be executed virtually. CROs and manufacturers accelerated these capabilities and embraced this change.¹⁹⁴

Janssen Pharmaceuticals launched an entirely virtual trial at the start of 2020 to understand the effectiveness of INVOKANA (canagliflozin) in adults with heart failure. Instead of in-person clinical visits, trial participants utilize digital platforms and tools to complete the studies. Medicine is delivered directly to a patient’s home, and patients are

FIGURE 8

Advantages of decentralized trials



Source: PPD.

required to provide guided assessments of their symptoms. These advances are changing the way clinical trials are done, while lowering patient burden and improving patient access.¹⁹⁵

“There is a lot of opportunity for more of us to participate in trials that are decentralized.”

— Valerie Paradiz, vice president of services and supports, Autism Speaks¹⁹⁶

HYBRID TRIALS OFFER FLEXIBILITY

When trial protocols require a qualified medical professional to physically meet a patient in person to conduct testing or perform specific interactions, a solely virtual program is not possible.¹⁹⁷ More trials will be hybrid trials—a combination of in-person and virtual visits. Prepandemic, hybrid models comprised 10–15% of all large biopharma trials. Hybrid trials now comprise 40–50% of all trials and may stay in that range for a while.¹⁹⁸

NEW TRIAL DESIGNS REQUIRE MORE RESOURCES

While hybrid or fully decentralized may be more convenient for patients, they require planning and additional resources, especially to address the needs of vulnerable or marginalized populations. Companies will have to determine which data points and collection tools are needed, as well as how logistics will be managed. This will likely take time and require buy-in from organizational leadership.

As a necessity, CROs have taken the lead in advancing decentralized and virtual trials. With COVID-19 continuing, and the decentralized trial capabilities accelerating, manufacturers predict only 41% of clinical trials will be traditional, onsite trials in 2021.¹⁹⁹ The other near 60% will be either hybrid or completely virtual and decentralized (figure 9).²⁰⁰ Manufacturers are expected to

continue outsourcing parts of their trials to CROs in the short term, until they build internal capabilities for hybrid and decentralized trials.²⁰¹

Data key in shift to transformative drug development approaches

The sector is finally at a point where advances in data science and analytics, capabilities, and desire are coming together and driving a big shift to transformative approaches in drug development.²⁰² Regulatory agencies are encouraging the use of novel approaches to expedite the development of new therapies.²⁰³

Companies that are further along in their adoption of transformative approaches tend to have portfolios heavily focused on oncology and/or rare disease. Lessons learned from oncology could be scaled to other therapeutic areas in a company’s portfolio.²⁰⁴ Biopharma companies should work collaboratively and transparently within the health care ecosystem and with data startups²⁰⁵ to unlock the data necessary to inform transformative approaches.²⁰⁶

Figure 10 depicts biopharma R&D products expected to be most promising in 2021. Setbacks could still affect any of these projects.²⁰⁷

THE NEXT FRONTIER FOR RWD ECOSYSTEMS

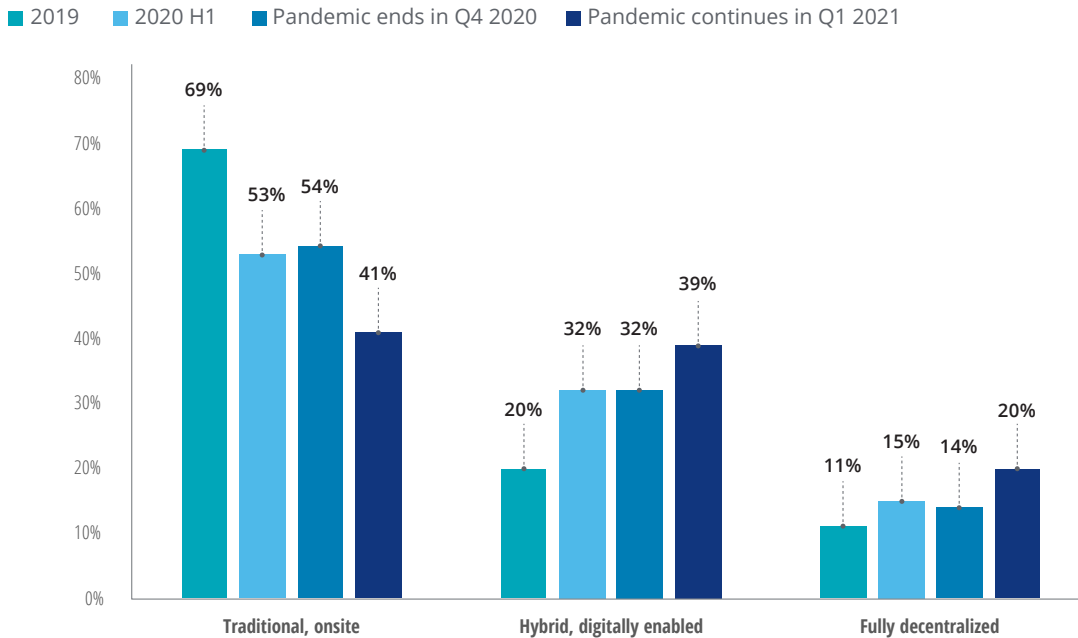
Compared to the rest of the world, the United States and Europe have more mature RWD ecosystems. Accessing RWD in the rest of the world presents unique challenges and, in most cases, will require partnering and significant effort. There can be limits to cross-border data-sharing, especially in emerging markets such as China and India.²⁰⁸

COVID-19 has accelerated the adoption of real-world evidence (RWE) as a way to test new

FIGURE 9

Advantages of decentralized trials

Of the clinical trials sponsored by your company from 2019–2021, please indicate the breakdown of trials (in percentages)—onsite, decentralized, or hybrid.



Source: PPD.

treatments more quickly. Rather than multiyear, longitudinal data that randomized clinical trials (RCTs) require, RWE coupled with RCT can enhance and increase the speed to insight.

The United Kingdom set up its RECOVERY trial for COVID-19—the world’s largest clinical trial into treatments for COVID-19—so that the data integrates with, and is reported through, the NHS DigiTrials platform. This allows researchers to link the clinical trial data and the collected RWE to more quickly shed light on the overall effectiveness of treatments.²⁰⁹ This hybrid approach led to the discovery that dexamethasone, a cheap and readily

available steroid, was shown to reduce deaths of hospitalized COVID-19 patients by one-third.²¹⁰

There remain barriers to RWE usage alongside RCTs as there is significant variability in the quality of RWE and its ability to support regulatory discussions. But progress certainly accelerated through experience with COVID-19.²¹¹

Unlocking an enablement of interoperable health care data is going to be the next frontier for improving R&D productivity and advancing life sciences insights. Finding ways to modernize data exchange among sponsors and multiple regulators

FIGURE 10

Biopharma's most valuable R&D products for 2021

Product	Company	Description	NPV
Tirzepatide	Eli Lilly	GLP-1/GIP dual agonist for type 2 diabetes; phase III ongoing.	\$12.7B
Lirentelimab	Allakos	Anti-eosinophil Mab for rare inflammatory gut disease; phase III ongoing.	\$8.2B
Deucravacitinib	Bristol Myers Squibb	Tyk2 inhibitor for psoriasis, autoimmune conditions; phase III ongoing.	\$6.01B
LN-144	Lovance	TIL cell therapy, melanoma lead indication; potentially registrational phase II trials ongoing.	\$5.3B
Sotorasib	Amgen	Kras G12C inhibitor for lung cancer; potentially registration phase II trial ongoing.	\$4.7B
Bempegaldesleukin	Nektar	Pegylated IL-2 for cancer; phase III ongoing.	\$4.4B
Tezepelumab	Amgen/Astrazeneca	Anti-TSLP Mab for severe asthma; phase III ongoing.	\$4.1B
Amivantamab	Johson & Johnson/Genmab	Anti-EGFR and CMet bispecific for lung cancer; phase III ongoing.	\$3.1B
CTX001	Vertex/Crisper	Ex-vivo Crispr-edited gene therapy for sickle cell and beta thalassaemia; potentially registrational phase I/II ongoing.	\$3.0B

Notes: Excludes COVID-19 products; all amounts are in US dollars.
Source: EvaluatePharma.

could enable regulatory filings across multiple geographies.²¹² More than 80% of pharmaceutical companies surveyed for Deloitte's annual

RWD/RWE benchmarking study say they are entering into strategic partnerships to access new sources of RWD.²¹³

LEVERAGING AI AND THE CLOUD

Applying AI and advanced analytics, life science companies should be able to understand earlier, and with more ease, what drugs work, and for what populations. AI could be leveraged to normalize data from various platforms (e.g., gene expression data) and to curate unstructured data types (e.g.,

GLOBAL DATA-SHARING PLATFORM TO SUPPORT INTERACTIONS BETWEEN INDUSTRY AND HEALTH AUTHORITIES WORLDWIDE

A new modern data exchange initiative, Accumulus Synergy, is bringing together 10 major biopharmaceutical companies for a global information-sharing platform that will support interactions between industry and health authorities worldwide. The cloud-based platform enables real-time collaboration and data exchange, as well as data submission.

The nonprofit aims to make the regulatory process more efficient by leveraging advanced technology and tools, modernizing the way drug innovators and health regulators interact. Data-sharing solutions should reduce the time it takes to make innovative new medicines available to patients.²¹⁴

images, clinical notes).²¹⁵ Investing in scalable cloud-based capabilities to access and analyze data that has been traditionally locked in silos across multiple organizations should enable a secure exchange of insights among research partners and collaborators.

DATA SCIENTISTS ARE A HIGH PRIORITY

Cultivating a talent pool of data scientists possessing both data science skills and drug development expertise is a high priority.²¹⁶ To



maximize the role of data scientists, companies should:

- Align data scientists to a therapy area and enable them to build a nuanced understanding of drug development in that area
- Embed data scientists as early as possible in study planning
- Partner data scientists with biostatisticians to enable cross-fertilization of ideas and experiences and help build long-term relationships
- Ensure data scientists comprehend regulatory science to better understand standards accepted by regulatory agencies
- Provide data scientists opportunities to develop their own ideas as well as career progression opportunities²¹⁷

Rethink clinical trials and collaborations:

- *How can trial designs better meet the needs of a diverse population? Are we involving all relevant stakeholders?*
- *What are the opportunities for decentralized or hybrid trials to drive better research and better patient outcomes and experiences? Are manufacturers embracing, accessing, and building the needed capabilities quickly enough?*
- *How can we support a global RWD ecosystem for higher-quality insights?*
- *What technologies can support the dearth in data scientists and make nondata individuals data-enabled?*

Shortening development and review timelines, thinking more like a regulator

Past experience and collaborations shape the future

In 2020, the US FDA kept its pace, approving 53 new drugs, compared to 48 in 2019.²¹⁸ The agency granted 72 first-time generic drug approvals²¹⁹ and 59 medical device approvals.²²⁰ At the same time, regulators were navigating the vital evaluation of tests, drugs, and vaccines in development for COVID-19.²²¹

As of December 16, 2020, more than 3,000 emergency use authorizations (EUAs) were submitted to the US FDA.²²² The agency reviewed over 2,300 EUA requests and provided EUAs to more than 600 products (e.g., therapeutics, vaccines, IVD tests, PPEs, ventilators, and other devices).²²³ Additionally, it revoked EUAs for a few KN95 masks, serology tests, and hydroxychloroquine on the basis of continuous risk-benefit monitoring studies. Prior to COVID-19, the US FDA issued 65 EUAs amid other public health emergencies.²²⁴

PAST EXPERIENCE ACCELERATES APPROVALS

Experience with existing regulatory pathways for expedited development helped inform the US FDA's approach toward COVID-19 drugs and treatment. EUAs enable therapies to be made available to patients faster. The European

Medicines Agency (EMA) uses the rolling review for vaccines, one of their expedited regulatory tools for emergencies that also includes rapid scientific advice, accelerated marketing authorizations, and compassionate use programs.²²⁵

Developers were allowed to use platforms approved in other areas, such as mRNA, for new development, provided they had the data to support it. Human trials of cancer vaccines using mRNA technology have been in use since 2011.²²⁶ Stability data was also allowed to be submitted after the fact, if the risk-benefit analysis was solid and safe, and vaccines for COVID-19 have had a very good safety profile to date.²²⁷

INCREASED COLLABORATION BETWEEN REGULATORY AGENCIES AND INDUSTRY

Vaccines forced a global population health perspective, and the approach has been very collaborative between regulatory agencies and industry. Cross-agency scientific resources enabled shorter review timelines for COVID-19 drugs and treatments.

The US FDA established a special emergency program for fast-tracking medicinal COVID-19 treatments, the Coronavirus Treatment Acceleration Program (CTAP). The program was designed to encourage collaboration with

researchers and share and streamline protocols, while deploying US FDA staff rapidly and effectively.

The European Commission (EC) and the EMA are critical collaborators for the US FDA. Together, they promote engagement with global regulators under the International Coalition of Medicines Regulatory Authorities (ICMRA) forum, comprised of 28 regulatory authorities from around the globe. The US FDA leverages inspection reports completed by the EU and United Kingdom under the Pharmaceutical Annex to the US-EU Mutual Recognition Agreement (MRA). The US FDA, EC, and other global partners also exchange information on medical device safety issues and regulatory developments.²²⁸

Despite these collaborations, local authorities are still making their own decisions. Several European countries suspended the use of AstraZeneca's coronavirus vaccine after reports of blood clots in some recently inoculated patients. However, the WHO said it was safe and urged countries to continue using it.²²⁹

The NIH/FNIH established the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Partnership, a consortium bringing together leading private biopharma companies with key government leaders and regulators to develop international regulatory best practices to help streamline and optimize the global scientific response to the pandemic.

In 2020, two drugs were also approved as part of Project Orbis, a framework for concurrent submission and review of oncology products among international partners to help identify any regulatory divergence between review teams.²³⁰

The agency says collaboration among international regulators may allow cancer patients to receive earlier access to products in other countries, regardless of whether the product has received US FDA approval.²³¹

Shortening timelines with run-on trials and RWD

With the desire to shorten new drug development and review timelines down, regulators are expected to feel the added pressure starting in 2021. Between 2010 and 2018, the mean average development and review time for a company to successfully move a product from the start of the clinical development process through to approval was 8.2 years.²³² However, the mean average development time was 6.7 years and the median was 5.6 years. The mean average review time was 1.5 years and the median was 0.9 years.²³³

Sponsors of COVID-19 vaccine and therapy treatments were encouraged to use novel strategies and technologies, including RWE, platform trials, remote clinical trial monitoring, and advanced analytics. Deloitte's RWD/RWE study finds that companies that invested in a centralized cloud-based analytics capability and knowledge management platform are at an advantage compared to those that are still building this capability. These tools can help organizations succeed in the new regulatory environment, compress timelines, and accelerate insights.²³⁴

The US FDA published final guidance on December 16, 2020, to provide sponsors and applicants information on how to interact with the agency regarding complex innovative trial design (CID) proposals for drugs and biologics.²³⁵

RUN-ON CLINICAL TRIALS MAY BE HERE TO STAY

For telehealth and remote clinical trials during COVID-19, regulators around the world worked hand in hand with industry rather than just having an endpoint type of review, and it is anticipated that this will be the case post-COVID-19.

A major difference for COVID-19 trials is that vaccine developers are entrusted with the evaluation of data results. They are able to advance to the next phase without delay, as long as endpoints are being met. However, the US FDA analyzes data in tandem with the next phase—already running—to save time in the process.

Good Manufacturing Practices compliance returns

Developers can expect a return to Good Manufacturing Practices (GMP) compliance. The US FDA and other regulatory agencies temporarily relaxed GMP compliance regulations for exceptional circumstances presented by the pandemic,²³⁶ such as when respiratory ventilators were in short supply.²³⁷

Manufacturers in other industries with idle plants jumped in to help with manufacturing and development at the beginning of the pandemic, benefitting from exceptions and the expeditious regulatory climate. These companies are not likely to continue in this vertical when they realize that the threshold for continued participation is much higher than originally believed. Only those companies committed to meeting the stringent quality requirements will be able to participate.

Some medical device companies also had extra capacity as a result of the decrease in elective surgeries. Many ramped up alternative production lines and worked overtime to produce personal protective equipment (PPE), ventilators, and the diagnostic tests desperately needed on the frontlines.²³⁸ Many lessons learned from the past will expedite paths for the future.

Future regulatory is digital and collaborative

Continued collaboration between governments, industry, and new players (e.g., Google, Apple, etc.) will likely fund innovative technologies for widespread diseases based on the model that evolved during the pandemic. Confidence in new technologies is expected to prevail, especially in mRNA technologies.

Outside players are likely to force the industry's legacy companies to become more digital in regulatory matters. Experts say that communications between sponsors and the US FDA need improvement to advance the uptake of 21st century regulatory science.²³⁹

In a 2021 report on the advancement of regulatory science, the US FDA says it is moving regulatory science into the 21st century. According to the agency, targeted investment in regulatory science research is necessary to facilitate development of innovative products, provide data and methods to inform regulatory decision-making, and improve guidance to sponsors.²⁴⁰

Thinking like a regulator

RISK-BASED APPROACH CORE TO REGULATORY OVERSIGHT

Stakeholders should review the US FDA's *Investigations Operations Manual*, updated in 2020.²⁴¹ Regulators take a risk-based approach in everything they do, and thinking like a regulator is key (figure 11).²⁴² While the thinking around risk/benefit analysis has stayed the same, the pandemic appears to have given more clarity to requirements and enabled greater speed. The aperture is wider now for risk analysis.

EUA letters and guidance for new drugs always mention that the agency has determined that benefits outweigh the risks for a particular product, and each case is different.

EUAs for COVID-19 vaccines were especially cautious—with administration to hundreds of millions. Safety was never compromised for the sake of expediting development. Even the perception that patient safety might have been compromised for expediency is detrimental for a vaccine and its acceptance.

Clinical trials in the cell and gene therapy space have skyrocketed, and developers are experiencing tough oversight due to the sheer number of trials. Demands on the US FDA will only grow. More than 1,200 phase 1–3 trials are currently underway globally, mostly in the United States and United Kingdom.²⁴³ For these therapies, knowledge continues to evolve as large bodies of data are collected during commercial manufacturing.

HOW TO THINK LIKE A REGULATOR

The best way to understand what a regulator wants is to study inspections and processes from the regulator's perspective, analyzing risks and benefits carefully.

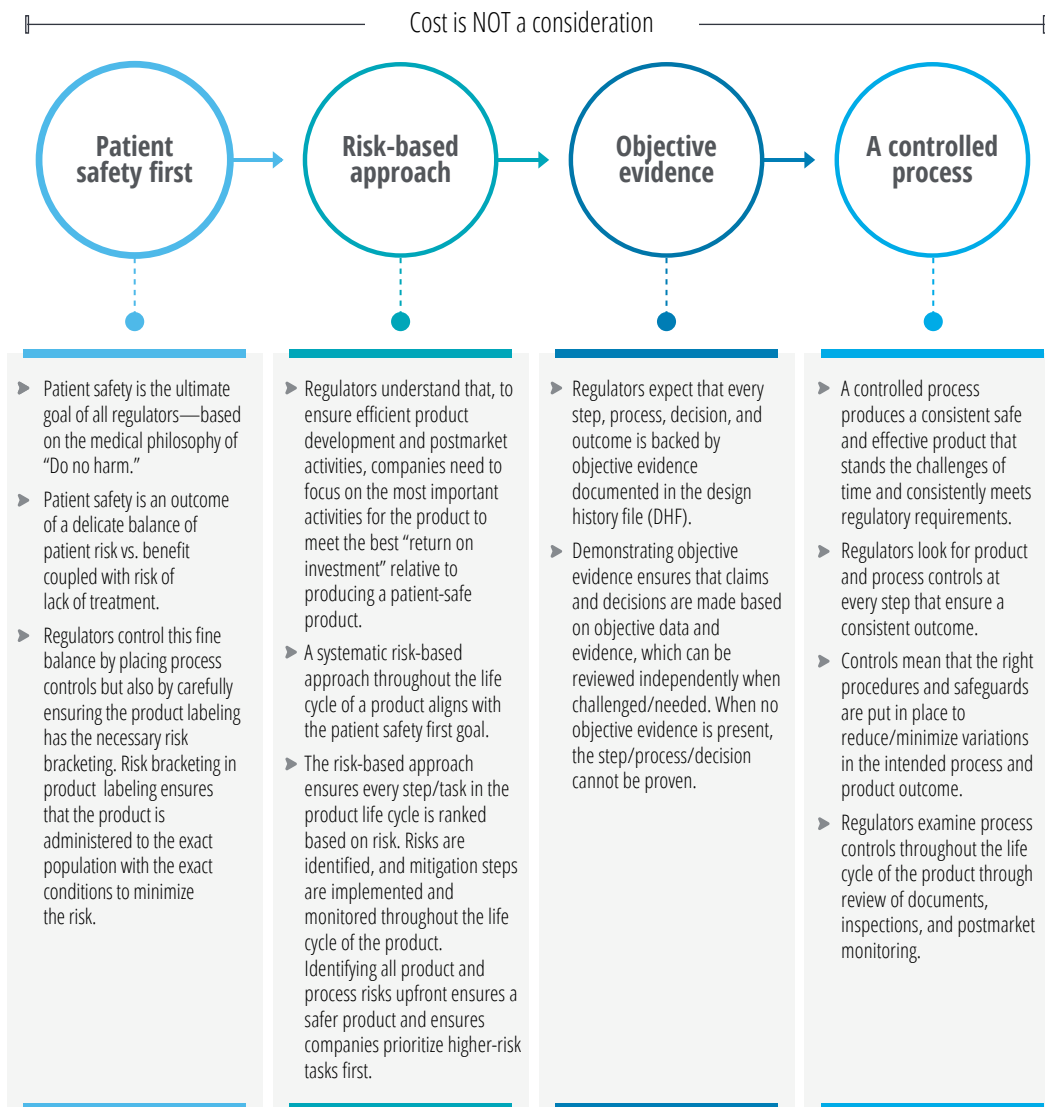
The agency wants to ensure that a company understands the risks specific to its product. By truly understanding the benefit/risk analysis, a company is more likely to answer a regulator's questions with confidence. Those who do not follow the format defined by the agency risk slowing the process down.

Rethink from the regulator's perspective:

- *How can our own risk-benefit analysis be improved?*
- *What more can we learn about the challenges of our product by adopting a risk-based view?*
- *How can digital improve our regulatory communications?*
- *Are we analyzing study inspections and processes from the regulator's perspective?*
- *Are we thinking like a regulator, or focusing more on what we think about our product?*
- *How can we streamline processes to facilitate run-on trials and shorten timelines?*

FIGURE 11

Think like a regulator



Source: Deloitte analysis.

Cross-border reliance intensifies the need for supply chain visibility and reshoring options

COVID-19 SHINED A light on cross-border reliance—in trade, manufacturing, and distribution.²⁴⁴ The need to vaccinate more than 70% of the world’s population placed a challenge on whether logistics would be as broad-reaching as needed, and equity issues still remain. To meet demand and accelerate time to market, vaccine manufacturers produced vaccines at risk. Further, special handling requirements for vaccines using mRNA technologies presented new challenges and required new solutions. Although companies believed they had resilient supply chains before the pandemic, what new lessons can be learned about resiliency?

Growing investments in reshoring

Having manufacturing and distribution facilities offshore has many advantages, but it also creates potential risks and vulnerabilities. Three major pharmaceutical companies, Pfizer, Amgen, and Bristol Myers Squibb, were severely impacted by Hurricane Maria in 2017. Currently, over 80% of pharmaceutical ingredients come from India and China, and the United States is increasingly relying on China and India for active pharmaceutical ingredients (APIs). To decrease foreign dependencies, there is a growing trend for bringing production back onshore, or reshoring.²⁴⁵

The current pandemic highlights the need to redesign supply chains and is creating a new level of urgency. Experts say that organizations should

evaluate their end-to-end supply chain plan holistically and include their strategic, operational, and financial leaders to optimize resiliency.²⁴⁶ In 2021, a significant amount of investment is expected to continue in reshoring, especially for capacity shortfalls (e.g., injectables, vaccines).

Medtech reallocates resources

In medtech, elective surgeries (e.g., hip and knee replacements, cosmetic surgeries, etc.) plummeted from March to August 2020. Volume suffered, and hospitals needed that space for COVID-19 patients. Lead time for suppliers was longer, and companies were required to hold more inventory. There were shipment delays and quarantine holds (e.g., products coming from China). Distribution issues extended to government warehouses. Manufacturers were reallocating resources and taking risks to mitigate the effects of the pandemic.

Manufacturing vaccines at risk

Because of the urgency of the COVID-19 pandemic, manufacturing for the COVID-19 vaccine was done at risk. “At risk” means vials of vaccine are manufactured to have them ready before it is known whether the vaccine works or not. Manufacturing is done in parallel with clinical trials and approval processes. If a vaccine is found not to have efficacy, all the vials would need to be destroyed. While potentially shaving years off the process, companies make a huge

financial investment manufacturing at risk.²⁴⁷ It is unclear whether this paradigm, or any part of it, could carry forward without these extraordinary circumstances and funding guarantees.

Pfizer did not receive government funding and took the risk of manufacturing the Pfizer/BioNTech vaccine without approval. The company says it wanted to protect its scientists from bureaucracy and ensure that they were free to focus on the scientific challenges.²⁴⁸ It was the first to receive EUA on December 11, 2020.²⁴⁹ Other vaccines were also manufactured at risk but received government funding.²⁵⁰

Competitors partner to expedite production and distribution of vaccines

Competitors are collaborating to boost vaccine demands amid supply constraints. In April 2020, the US Justice Department and Federal Trade Commission issued a joint statement detailing an expedited antitrust procedure and providing guidance for business collaborating to protect American lives during the coronavirus outbreak.²⁵¹

Novartis is slated to produce Pfizer/BioNTech's rival mRNA vaccine at Novartis' manufacturing facilities in Stein, Switzerland starting in Q2 2021.²⁵² Novartis will take bulk mRNA active ingredients from BioNTech to fill vials under aseptic conditions for shipment back to BioNTech for their distribution.²⁵³

Novartis will also be part of CureVac's European manufacturing network that includes Bayer, GlaxoSmithKline, and several other companies.²⁵⁴ However, CureVac's candidate, CVnCoV, is still in clinical testing. CureVac plans to produce 300 million doses in 2021, and up to 600 million doses in 2022, to fulfill its European supply order.²⁵⁵

Johnson & Johnson is getting vaccine manufacturing support from Sanofi at its vaccine

manufacturing plant in Marcy-l'Étoile, France. Sanofi plans to formulate and fill vials of Johnson & Johnson's Janssen COVID-19 vaccine at a rate of approximately 12 million doses per month.²⁵⁶

The US administration invoked a partnership between Johnson & Johnson and its pharmaceutical competitor, Merck, to expedite vaccine production and distribution. Merck is using capabilities earmarked for its own vaccine. Leveraging unutilized capacity makes the collaboration economically possible.²⁵⁷

Big pharma manufacturing for other pharma companies is apparently not as unusual as it may seem. When internal capacity is strained, companies talk to other companies that may have the capacity to support their supply chain—especially for a blockbuster drug. Options from contract manufacturing organizations (CMOs) may also not be available or feasible.²⁵⁸

The Associated Press found three factories on three continents whose owners say they could start producing hundreds of millions of COVID-19 vaccines. But first, they need the blueprints and technical know-how. One factory in Bangladesh has brand new equipment from Germany and is operating at a quarter of its capacity. The debate on intellectual property rights is a likely barrier to manufacturing. Some say the solution to vaccine shortages in emerging markets is distributing more vaccines from rich countries to poor countries.²⁵⁹

Changes in manufacturing and supply chain are driving the need for new partnerships,²⁶⁰ and companies should collaborate with others to ensure the consistent delivery of product into the market.²⁶¹ The supply chain for vaccines relies on public-private partnerships and institutional trust. Gavi, the WHO, the Coalition for Epidemic Preparedness Innovations (CEPI), and more than 180 countries joined the COVAX initiative to ensure vaccines are available to all countries, rich or poor.²⁶²

EXPANDING ACCESS TO DATA FOR SUPPLY CHAIN EFFICIENCY OR PERSONALIZED CARE

Palantir's Foundry software claims it can help global institutions tackle crises and disruptions with data. The technology uses a company's data to increase supply chain visibility without needing to rely on data scientists and engineers. Although the data analytics company uses highly advanced technologies, including AI, Foundry can be integrated into other software tools that businesses already have.²⁶³ Leveraging current systems in new processes helps to achieve operational excellence.²⁶⁴

Data can be searched and analyzed from a wide range of sources. The infusion of new data enables organizations to see things that were always there, but previously impossible to observe or quantify.²⁶⁵ For example, by pinpointing unused raw materials, excess inventory might be turned into sales opportunities. In health care, scientists have used Foundry to provide a full-scope view of cancer patients for personalized care. The software is used by Sanofi and Merck, among others.²⁶⁶

Innovative science driving the need for new manufacturing capabilities

Vaccines had not changed much prior to a year ago. To trigger an immune response, most vaccines deliver a weakened or inactivated germ into the body. The new mRNA vaccines teach cells how to make a protein (or a piece of a protein) to trigger an immune response.²⁶⁷ The success of the Pfizer/BioNTech and Moderna mRNA-based COVID-19 vaccines is paving the way for more innovation to come. If mRNA can be used, not just for vaccines, but for cancer cells,²⁶⁸ it may be one of the most exciting therapies since the polio vaccine.

In simplified form, viral vector vaccines are engineered viruses used to deliver therapeutic genes to the body. The body develops a specific immune response without needing to have the infection. The Johnson & Johnson/Janssen Pharmaceuticals and Oxford-AstraZeneca COVID-19 vaccines are viral vector vaccines. The massive growth of gene therapy research and development has boosted demand for viral vectors and advanced

manufacturing capabilities.²⁶⁹ The next innovation in cell and gene therapy is predicted to be achieving stable producer cell lines for viral vector production.²⁷⁰

Viral vector and mRNA medicines are hard to manufacture, and manufacturing processes need to improve. Rapidly optimizing both manufacturing processes and therapeutic product performance will require bringing together genomics information, clinical information, and manufacturing information.

Novartis, Pfizer, and Fujifilm have ramped up investments in gene therapy manufacturing. Contract manufacturers such as Catalent and Thermo Fisher Scientific are also expanding operations to support gene therapy R&D.²⁷¹

Contract manufacturing agreements are growing for next-generation therapies. A lot of pharma companies will need to leverage their partners instead of manufacturing the products themselves. The rapid ability of contract manufacturers to scale is going to continue.

What to expect post-COVID-19

Who responded the best during the first wave of the pandemic? The answer is simple: the companies that had invested the most in supply chain processes and capabilities before the crisis.²⁷² Increased demand and supply volatility are expected,²⁷³ and remaining competitive is an imperative for building resiliency.²⁷⁴ Companies should invest in:

- Supplier visibility, to better understand the risks their network of suppliers may face
- Digital and analytics capabilities, to rapidly present information to decision makers²⁷⁵

Companies realize that enhancing visibility, and the underlying technologies and capabilities that support them, are essential for improving integrated business planning.²⁷⁶

Potential ways to improve supply chain visibility:

- Gain an understanding of the upstream supply chain, not just suppliers, but your supplier's suppliers
- Use technology for real-time visibility of the internal supply chain, logistics, and distribution—move away from manual, labor-intensive processes

- Gain more real-time visibility of product moving through the transportation network

Rethink supply chain resiliency:

- *Are there areas and/or ways to do some degree of manufacturing at risk for select patient populations or situations that merit such risk-taking? What can we leverage to make our competitive relationships more collaborative?*
- *Have we incorporated the right lessons learned from the pandemic and supply chain resilience?*
- *What benefits could reshoring provide? What risks?*
- *How can our continuity plans be improved?*
- *How can better visibility lead to new opportunities?*
- *How can we use new technologies for better process and supply chain visibility?*
- *What regulatory, funding, and innovation lessons could we apply from our collective COVID experience?*

Advancing humanity: Environment, social, and governance (ESG) imperatives

B EING A GOOD corporate citizen is about leading with *purpose*, and the impacts a company's operations have as a whole on environment, social, and governance concerns.²⁷⁷ Leading with purpose helps create collective value for all stakeholders, including shareholders.²⁷⁸ Leading with purpose and advancing humanity—not *alongside* one's core business operations, but *inside* one's core business operations—will be an essential part of overall success.

"Society is best served by corporations that have aligned their goals to serve the long-term goals of society."

— International Business Council of the World Economic Forum²⁷⁹

Rising to a new role in society

Many industries experienced rapid changes in reputation during the pandemic, but none perhaps as drastic as the life sciences sector.²⁸⁰ The pandemic made household names of life sciences companies, large and small,²⁸¹ and some of these companies are now among the top 20 fastest-growing brands, according to Morning Consult.²⁸²

With the sector on its front foot, how can companies build more trust²⁸³ and drive more growth for good? What opportunities have emerged for companies to take a more comprehensive approach and deepened

commitment to integrating trust in all they do? More than being good corporate citizens, organizations can lead by example, operate with integrity, build a secure foundation, deliver on patient-centricity, and innovate without borders (figure 12). They have an opportunity to meld trust objectives into their core business and DNA.

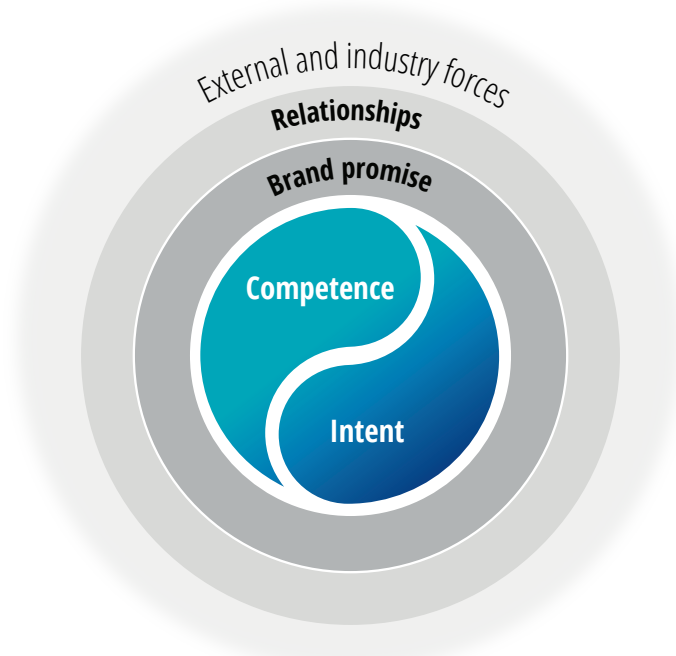
CREATING SUSTAINABLE, COLLECTIVE VALUE

Measuring ESG progress is critical to building trust and advancing the sector's role in society. Companies that have already built ESG strategies, measurements, and high-quality disclosures into their business models are likely to be well positioned to capitalize on opportunities and drive long-term value post crisis.²⁸⁴ The pandemic generated considerable attention to social issues and highlighted gaps and needs across the range of these issues.

Some life sciences companies have either directly or indirectly embraced ESG evaluation and criteria as a mechanism to attempt to lead in society and hold themselves more accountable. Novartis uses ESG as a core component for how its executive committee and board of directors evaluate long-term performance and provide detailed reporting in its annual report as well as other publications.²⁸⁵ Johnson & Johnson's annual *Health for humanity report* is available in several languages and represents a broad range of ESG issues that are important to the company and its stakeholders.²⁸⁶

FIGURE 12

Life sciences trust framework



Competence + intent				
<p>Lead by example</p> <ul style="list-style-type: none"> • Alignment between leadership and board • Authentic and resilient leadership • Strong governance, scenario planning, and crisis response • Transparent internal and external communications 	<p>Innovate without borders</p> <ul style="list-style-type: none"> • Deep disease and patient understanding • Innovations addressing unmet needs • Ethical use of AI • Patient-centric clinical trials • Good data governance 	<p>Operate with integrity</p> <ul style="list-style-type: none"> • Consistent drug availability • Strong value chain risk management • Integrity in partnerships • Sustainable and secure supply chain • Intelligent manufacturing processes and quality control 	<p>Secure the foundation</p> <ul style="list-style-type: none"> • Compliance and conduct • Cybersecurity strategy and resilient operations • Technology and infrastructure security • Empowered workforce • Strong environmental and social governance 	<p>Deliver with patient-centricity</p> <ul style="list-style-type: none"> • Humane digital engagement • Early, consistent, and transparent engagement • Transparent and fair pricing aiming for health equity • Data-led intelligence and evidence dissemination

Source: Deloitte analysis.

ESG factors are becoming a key determinant of a company’s financial strength. ESG is important to millennials, Gen Z, and boomers. Boomers say that they participate in ESG investing to encourage

companies to be good corporate citizens.²⁸⁷ Business ethics, product governance, and access to basic services are key issues that could impact valuations of big pharma and biotech companies.²⁸⁸

Environment: Becoming a renewable and sustainable organization

In the midst of a crisis, priorities typically shift. But research shows that COVID-19 has not made people any less concerned about global climate change.²⁸⁹ Major companies continue to make pledges to reduce or eliminate their carbon footprints.²⁹⁰ The reallocation of capital to sustainable assets accelerated more rapidly than ever,²⁹¹ and CEO activism may drive impact from a very personal level.²⁹²

Human activities are the most significant driver of climate change. The best way to reach and maintain sustainability may be a collective, timely, and strategic focus on our human and societal values.²⁹³ What we do collectively in the next 50 years may affect the next 10,000.²⁹⁴

“Companies with a well-articulated long-term strategy, and a clear plan to address the transition to net zero, will distinguish themselves with their stakeholders—with customers, policymakers, employees and shareholders—by inspiring confidence that they can navigate this global transformation. But companies that are not quickly preparing themselves will see their businesses and valuations suffer.”

— Larry Fink, CEO, BlackRock, 2021 letter to CEOs²⁹⁵

ACHIEVING “NET ZERO”

A recent report by the European Commission shows good progress in strategies to reduce the adverse effects of pharmaceuticals on the environment.²⁹⁶ In 2020, Novo Nordisk achieved its target of using 100% renewable power across its

global production and is now working with 60,000 of its direct suppliers to go 100% renewable by 2030.²⁹⁷ Takeda achieved carbon neutrality with offset projects across 12 countries in 2020.²⁹⁸

Reducing pollution through pharmaceutical production is just one of many areas the sector is addressing.²⁹⁹ A sustainability bond provides investors with a reporting on environmental or social projects that have been financed by using the bonds’ proceeds and is a vehicle to attract more investment for sustainable projects.³⁰⁰

In September 2020, Novartis reinforced its commitment to ESG principles with a EUR€1.85 billion sustainability-linked bond (SLB) that incorporates social targets. Bondholders are entitled to receive a higher amount of interest if Novartis:

- Fails to meet its targets for expanding access to its innovative medicines
- Fails to address key global health challenges³⁰¹

“Our continued investment in our planet supports our purpose to reimagine medicine to improve and extend people’s lives. It is also a way to build trust with society, if our actions are guided by a commitment to transparency and creating enduring change.”

— Novartis³⁰²

One-third of the 280 leading companies supporting the Climate Group’s global initiative, RE100, are from the biotech, pharma, and health care industries. The Climate Group surveyed its members and released a comprehensive annual report on renewable energy insights in December 2020, outlining barriers in challenging markets (figure 13).³⁰³

FIGURE 13

Challenging markets and barriers for renewable energy reported by RE100 members

Number of members citing the barrier

■ High ■ Medium ■ Low

	China (mainland)	Singapore	South Korea	Russia	New Zealand	Argentina	Taiwanese market	Japan	Indonesia	Australia
Electricity demand of members citing market barriers (MWh/yr)	877,220	522,581	162,221	405,821	141,779	489,101	74,825	194,279	389,176	135,541
Number of members citing barriers in that market	18	16	14	13	13	12	12	12	11	11
Total number of members in that market	82	62	49	42	36	42	46	76	48	69
Limited/no availability	High	High	High	High	High	High	High	High	Low	Low
Regulatory barriers	High	Low	High	High	Low	Medium	Low	Medium	Low	Low
Cost	Low	High	Low	Low	Low	Low	High	High	Low	High
Small load	Low	Low	Low	Low	Low	Low	Low	Low	Low	Medium
No certificates available to purchase	Low	Low	Low	Low	High	Medium	Low	Low	Low	Low
Cost of certificates	Low	Low	Low	Low	Low	Low	Medium	Low	Low	Low
Lack of PPAs	Medium	Low	Low	Low	Low	Low	Low	Low	Low	Low
Leased offices	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low

Source: The Climate Group, RE100.

PHARMA COMPANIES SHIFTING TO ELECTRIC VEHICLES




As *purpose* continues to rise to the top of corporate agendas, an increasing number of pharmaceutical companies are shifting to electric vehicles (EV) as a force for positive change. Business travel is a major avenue for businesses to alleviate emissions.³⁰⁴ The Climate Group’s EV100 members are committed to

switching their fleets to electric vehicles and installing charging infrastructure for employees and customers by 2030; six are pharmaceutical companies (figure 14).³⁰⁵ EVs are currently driving an infrastructure charging boom.³⁰⁶

While it is important for life sciences organizations to invest in changes to operations that reduce

FIGURE 14

Life sciences companies committed to reducing gas emissions via EV100

 Company	 EV transition goal	 Charging infrastructure goal
AstraZeneca	16,000 vehicles by 2025	
Biogen	1,605 vehicles by 2030	Charging for staff at 30 corporate locations
Genentech	1,300 vehicles by 2030 and 100% of bus fleet by 2025	Charging for staff
GlaxoSmithKline (GSK)	19,000 vehicles by 2030	Charging for staff at 100 locations
Novartis	25,000 vehicles to low- to zero-emission vehicles by 2025	
Novo Nordisk	8,000 vehicles by 2030	

Source: The Climate Group, EV100.

environmental impact and reduce greenhouse gas (GHG) emissions, they should also focus on areas of environmental and social impact that are most material to their core business. In particular, they should focus on mitigating both the effects of climate on new disease vectors³⁰⁷ and the current, compounding health inequities.³⁰⁸

GROWING INFLUENCE OF MILLENNIALS AND GEN Z IN ENVIRONMENTAL AND SOCIAL CONCERNS

Deloitte research finds that millennials and Gen Z continue to push for a world in which businesses and governments mirror their commitment to society—putting people ahead of profits and prioritizing environmental sustainability.³⁰⁹ Climate change and health care/disease prevention were top concerns for 27,500 participants surveyed before and during the pandemic.³¹⁰

Strategist Haim Israel believes the impact of Gen Z is an underestimated, upcoming tsunami. “Gen Z is going to bring broad disruptions to economies, markets and social systems. If they haven’t done so already, businesses and investors need to start

adjusting their strategies to reflect Gen Z’s growing political, social, and economic influence,” he says.³¹¹

The Gen Z cohort typically:

- Is willing to pay more for eco-friendly and sustainable products³¹²
- Wants access to data and transparency about chemicals and their presence in products³¹³
- Tracks its carbon footprints and supports carbon offsets³¹⁴

“Some people don’t want to think it’s true that humans are causing this damage. We are responsible for what has happened and what will happen. But I’m carbon neutral, so every month, I invest in a project that offsets my carbon footprint.”

— Anna Hursey, United Nations Framework Convention on Climate Change (UNFCCC) Young Champion, 14-year-old Welsh table tennis prodigy with asthma

Carbon offsets generate funding for environmental projects that otherwise couldn't exist.³¹⁵ The United Nations' (UN) carbon offset platform supports UN-certified Clean Development Mechanism (CDM) projects across the globe impacting environmental, economic, and social challenges in the developing world.³¹⁶

Social: Achieving equity in health, race, and gender

MOVING FROM EQUALITY TO EQUITY, THEN JUSTICE

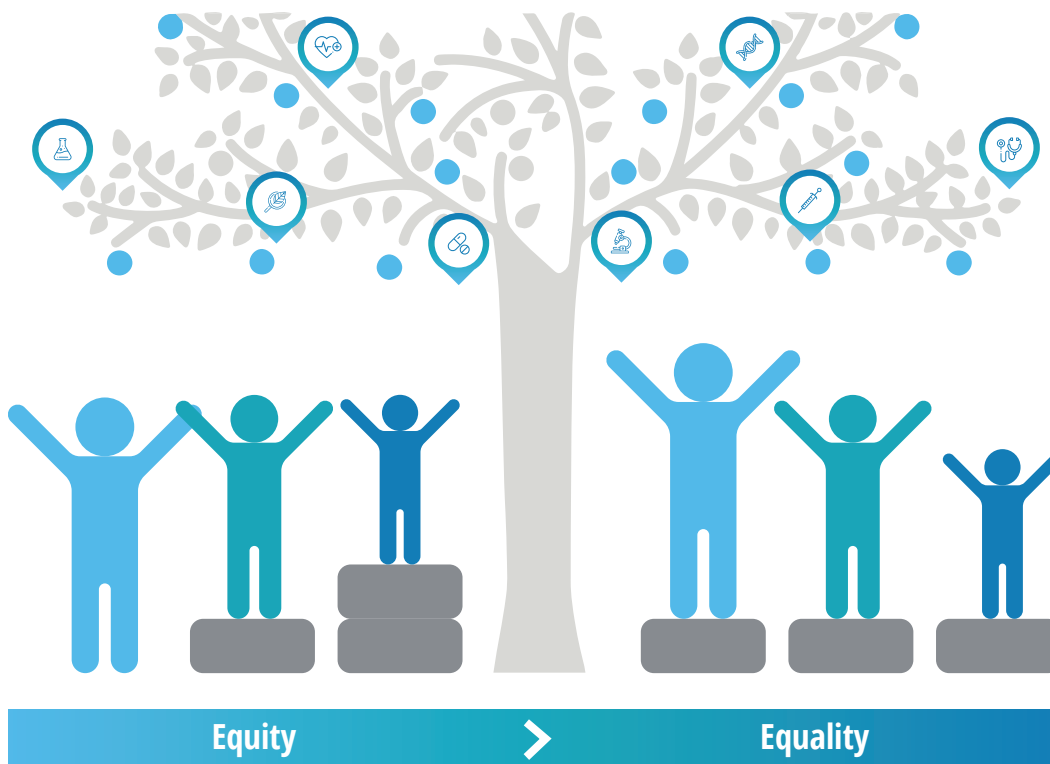
The pandemic exposed many inequities in our systems, our human frailties, but also our collective

strengths. Understanding the difference between equality and equity is critical for driving change. Equality is treating everyone identically. Equity recognizes that each person has different circumstances and allocates the exact resources each individual needs to reach an *equal outcome*.³¹⁷

Figure 15 demonstrates the difference between equality and equity—visualized as the ability to reach fruit from a tree.³¹⁸ Even when each person receives an equal level of support, their access to the fruit remains unequal. The equitable solution allocates the exact resources that each person needs. One person may need one level of support, another two, and the third, three—to achieve positive outcomes for all three individuals.³¹⁹

FIGURE 15

Visualizing the difference between equity and equality



Source: NASTAD.

HEALTH EQUITY

Health is a human value

Health inequities are amplified in the disproportionate number of deaths in Black and disadvantaged communities from COVID-19.³²⁰ The sector's focus for 2021 should be on access, reach, and equity for all. According to the WHO, differences in equity can be social, economic, demographic, or geographic. Health equity addresses these underlying issues and the individual needs of underserved and vulnerable populations.³²¹

Health equity requires meeting people where they are with the necessary resources to maintain or improve health outcomes.³²² According to Carmen Villar, vice president of Social Business Innovation for Merck, "Industry has a significant role to play in health equity through economic inclusion, fighting for social justice, and strengthening the global communities it serves."³²³

Diversity in clinical trials

Diverse patients account for less than 10% of patients enrolled in clinical trials.³²⁴ It is important that a study population is representative of the population that may ultimately use a drug or therapeutic.

In 2019, the US FDA approved 11 new cancer drugs, but only 4% of the participants enrolled in those clinical trials were Black. This group also has the highest death rates for most cancers. The communities hardest hit by COVID-19 are also grossly underrepresented in trials, yet essential for developing safe and effective vaccines and cures.³²⁵

More diversity in clinical trials—and across all of medicine—could improve health equity.³²⁶ As part of its US\$300 million diversity initiative, Bristol Myers Squibb (BMS) plans to train 250 new racially and ethnically diverse clinical trial investigators and extend the reach of its trials to underserved rural and urban communities.³²⁷

Health equity for patients should be delivered across the value chain—addressing who is reached, what is ultimately developed through clinical trials, and who has access to these clinical trials, medicines, and treatments—no matter what the condition or disease.

We discuss diversity in trials in more detail in the R&D section of this report, including how new trial designs may enable broader access and increased participation.

Justice takes equity one step further—fixing systems in a way that may lead to long-term, sustainable, and equitable access for generations to come.³²⁸

RACIAL EQUITY

According to Courtney Christian, a senior director of policy and research at PhRMA—the Pharmaceutical Research and Manufacturers of America—racial injustice and the lack of equal access to quality health care are rooted in systemic racism.³²⁹ Systemic racism is reflected in disparities in wealth, income, employment, housing, health care, political power, education, the criminal justice system, and other factors.³³⁰

As systemic problems, racial and health inequities require a systemic response. Organizations should challenge orthodoxies—unstated assumptions that may go unquestioned—that are embedded in company culture. Racial equity requires a constant, sustained commitment from leaders and team members utilizing the full breadth of their power and influence across the organization.³³¹

COVID-19 had a disproportionate effect on Black and Brown communities,³³² and PhRMA member companies have become more aware of their collective impact on communities of color. "We knew that, as an industry, we needed to step up our ongoing effort to be better corporate citizens in communities of color," Christian says.³³³

In addition to clinical trial diversity initiatives, PhRMA members joined more than 1,100 companies in signing a CEO Diversity and Inclusion Action Pledge to advance diversity and inclusion in the workplace.³³⁴

DIVERSITY + EQUITY + INCLUSION (DEI)

Employment equity encourages fair and equitable representation, training, and promotion in the workplace, particularly for disadvantaged groups.

In 2021, Deloitte, along with many companies, added *equity* to their diversity and inclusion framework.³³⁵ DEI is not just a project or an initiative—or even the sole responsibility of HR—but the way an entire company behaves.³³⁶

The killing of George Floyd in the United States moved the world, uniting people to decry racism.³³⁷ It also reawakened corporate America to the issues of social justice.³³⁸ Ken Frazier is chairman and CEO of Merck and believes that the nexus between

corporate America and what Black America needs the most is employment. As one of only four Black CEOs leading a Fortune 500 company, he says, “If we can do something about the 5.5 million African Americans between 18 and 26 who have a high school degree or a GED, but no college and no job, we would make a big impact on this. We have to have the psychological armor to defend ourselves against the racism that’s all around us.”³³⁹

OneTen.org is a coalition of leading companies committed to developing 1 million careers for Black Americans over 10 years. Executives are working with nonprofits who support development of diverse talent and have a skills-first focus for creating family-sustaining jobs and earned success. Life sciences and medtech companies that are part of the coalition include: Amgen, Eli Lilly, Gilead Sciences, Johnson & Johnson, Merck, Medtronic, and Stryker.³⁴⁰

INITIATIVES ACCELERATING THE RACE TO HEALTH EQUITY AND SOCIAL JUSTICE

Palantir’s Foundry software claims it can help global institutions tackle crises and disruptions. Companies have stepped up, allocating significant investments to reduce inequities. These initiatives go beyond philanthropy and aim to accelerate meaningful change and demonstrable results.

Johnson & Johnson is committing US\$100 million over the next five years to invest in and promote health equity solutions.³⁴¹ The company views racial and social injustice as a public health threat. One of many initiatives is strengthening community health for people of color in the United States by providing technology and mobile health solutions in partnership with Community-Based Clinics and Federally Qualified Health Centers.³⁴²

BMS and the Bristol Myers Squibb Foundation first devoted time listening to the challenges faced by the Black/African American community after the death of George Floyd. Then, they committed US\$300 million to programs that would best address racial injustice and health inequities over the next five years. In addition, US\$1 billion will be spent globally by 2025 to advance Black/African American and other diverse-owned businesses—creating jobs and generating positive economic impact in communities impacted by systemic injustices.³⁴³

PhRMA launched industrywide principles on clinical trial diversity.³⁴⁴ The aim is to earn trust and address systemic issues that deter Black and Brown communities from participating in clinical trials. The principles address protecting research participants, conduct for clinical trials, objectivity in research, providing information about clinical trials, expanding access to investigational drugs, and enhancing diversity in clinical trial participation.

The Business Roundtable’s CEOs represent some of the largest companies in the United States, committing to driving real change for racial justice and equity.³⁴⁵ New proposals have been developed by 208 members addressing what more can be done, including an improved pandemic response.³⁴⁶

GENDER EQUITY

While hundreds of millions of people worldwide lost their jobs as a result of the pandemic, in many countries, women were hit the hardest (figure 16).³⁴⁷ In Japan, loss of jobs were heavily sector-related,³⁴⁸ while in the United Kingdom, many women completely opted out of returning—even when lockdowns were lifted.³⁴⁹ In the United States, almost 3 million women left the workforce in the past year, many overwhelmed by lack of childcare resources and other pressures.³⁵⁰

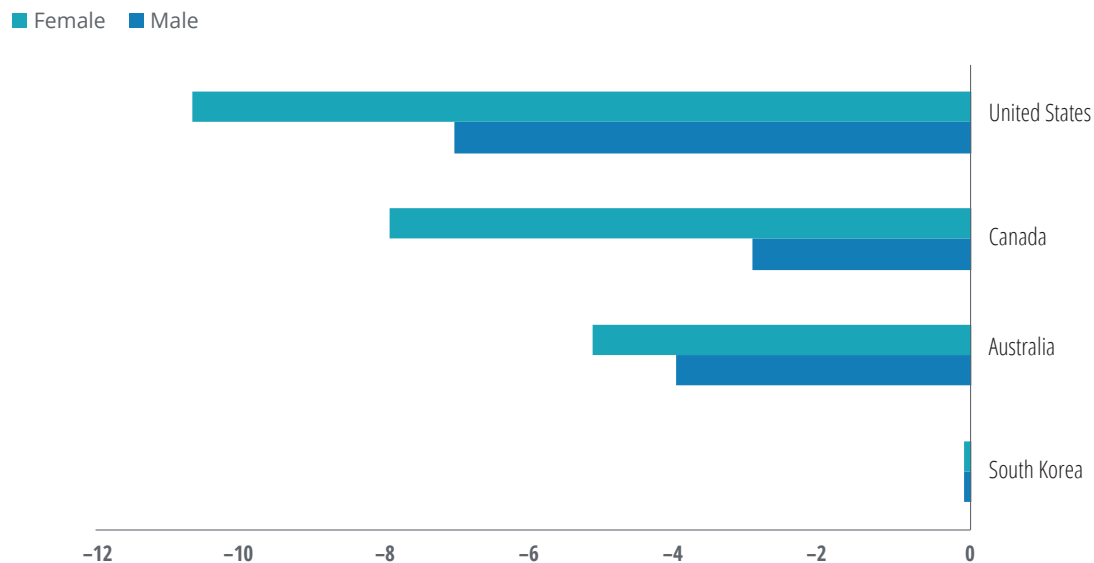
According to the Institute for Women’s Policy Research, an employment gap of just one year may lead to an almost 40% decrease in annual earnings and reduces women’s chances of becoming future leaders in society.³⁵¹ This adds to the challenge in 2021, as companies look to prioritize advancing more women and women of color into the C-suite and onto corporate boards.³⁵²

Deloitte surveyed nearly 400 working women across nine countries to understand how some working women have been impacted by the pandemic. Nearly seven out of 10 women who experienced negative shifts in routine believe their career progression will slow down. In suggesting improvements employers could provide, answers varied. Women without caregiving responsibilities stressed the need for more skills-development and learning opportunities, in addition to more access to senior leadership. Working mothers, on the other hand, were more focused on better benefits such as sick leave or parental leave.³⁵³

Gender equity ensures opportunities are not limited on the basis of gender and corrects for gender biases. It may include treatment that is different, but considered equivalent, for rights, benefits, obligations, and opportunities.³⁵⁴

FIGURE 16

Percentage change in the number of employees by country, July 2020 compared to December 2019



Source: International Labor Organization.

Governance: Measuring progress for accountability

While bold and transformative steps are needed to shift the world onto a sustainable and resilient path, highlighting actions is not enough. Companies should put numbers to these impacts. Measuring ESG progress makes organizations accountable and shows areas for improvement. In particular, tracking impacts may:

- Better inform the organization as a whole
- Better inform all stakeholders, including shareholders
- Help deliver equitable outcomes
- Advance society and the totality of an organization³⁵⁵

As a company tracks its progress, it will need to become comfortable with increasing transparency. The US Government Accountability Office (GAO) has expressed concern about ESG reporting. Some companies may disclose details about steps they are taking to manage ESG-related risks or opportunities, but do not discuss the results.³⁵⁶ The US Securities and Exchange Commission (SEC) formed a Climate and ESG Task Force to identify misconduct in ESG reporting.³⁵⁷

In reporting nonfinancial progress on ESG goals, US companies fail to match top scores of international companies based in Europe and Australia. According to a recent study, 19 out of 30 Dow Jones Industrial Average companies from the United States ranked in the bottom 50% of 140 companies analyzed by Global ESG Monitor worldwide.³⁵⁸

Public and private investors are increasingly making their own demands. The Vanguard Group, a leading mutual fund company, published expectations for public companies to disclose board diversity measures and progress made toward increasing the diversity of their boards.³⁵⁹

CREATING NEW KPIS FOR ENGAGING PATIENTS AND COMMUNITIES

Socially responsible companies are creating new key performance indicators (KPIs).³⁶⁰ Takeda has a new metric for assessing the patient perspective in R&D—requiring all global program teams to include a patient engagement activity as a KPI. The KPI has evolved over the last three years:

- 2019: Team set a goal to have employees fulfill three patient-themed activities that would bring the individual employee closer to patient perspectives
- 2020: KPIs required each global program team to include a patient engagement activity goal
- 2021: All teams need to have an overarching road map for engaging patients and patient communities (“patient engagement plan”)

“Our innovative model of creating a push and pull by tying patient engagement requirements to KPIs is resonating across the organization. We are connecting patient activities to every global team while giving the teams flexibility with the activities they come up with—without being prescriptive. We want to allow for teams to be really innovative and to focus on activities that are of value to the development of the compound.”

— Jessica Scott, MD, head of R&D Patient Engagement Office, Takeda

Takeda is the winner of the EURORDIS 2021 Award for Patient Engagement in recognition of the company’s commitment to rare disease patients and its partnerships with the rare disease patient community.³⁶¹

THE WORLD ECONOMIC FORUM CREATES NEW METRICS FOR REPORTING ON ESG

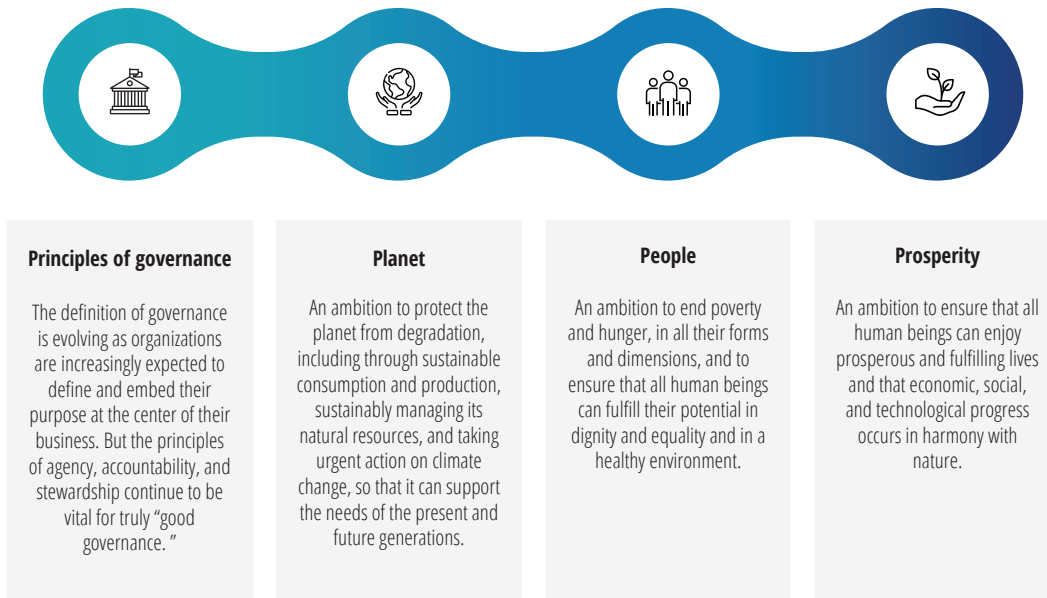
The private sector has a critical role to play in ESG. In 2020, the World Economic Forum (WEF) and its International Business Council (IBC) identified the need for new metrics and consistent reporting of sustainable value creation. Working in collaboration with Bank of America, Deloitte and other professional services organizations, they identified four pillars (figure 17) that have an important bearing on the capacity of a firm to generate shared and sustainable value—*principles of governance, planet, people, and prosperity*.³⁶²

This work defines a core set of “Stakeholder Capitalism Metrics” (SCM) and disclosures that can be used by the WEF’s International Business Council members. The set contains 21 core and 34 expanded metrics that were curated more than two years with the support of over 140 stakeholders.³⁶³ The goal is to align mainstream reporting on performance against ESG indicators and track contributions toward the Sustainable Development Goals on a consistent basis.³⁶⁴

Success today and in the future depends on collaborating for *shared value* in a way that is transparent and sustainable. According to Erich Joachimsthaler, author of *The Interaction Field*, businesses need to create shared value for everyone, and success depends on the ecosystem. He says, “Businesses that solve immediate challenges of people today, and also the major social and economic challenges of the future, are the ones that will survive and grow.”³⁶⁵

FIGURE 17

Four pillars of sustainable value creation



Source: World Economic Forum, *Toward Common Metrics and Consistent Reporting of Sustainable Value Creation*, January 2020.

Rethink ESG and measuring progress:

- *What are the opportunities to make us a better social enterprise?*
- *How can the rising importance and clarity of ESG objectives be used to accelerate social progress?*
- *How are we measuring ESG impacts and risks? What can accelerate progress in ESG?*
- *Where do we need to move from equality to equity?*
- *How can we use the full breadth of our power and influence to overcome health, racial, and gender inequities?*
- *How are we creating sustainable shared value for everyone in our ecosystem and society as a whole?*
- *Are we taking a comprehensive and sustained approach to sustaining trust with society? Where are our greatest risks regarding building on or harming the trust we have established this past year?*



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The authors would like to thank **Terry Koch** of Deloitte Touche Tohmatsu Limited, **Sarah Thomas** of Deloitte Services LP, **Karen Thomas** of Deloitte LLP, and **Angela Dunn** for their contributions to this report.

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SHORT TAKE

2021 global life sciences outlook

Possibility is now reality,
sustaining forward
momentum

THE 2021 GLOBAL life sciences outlook looks at the many ways COVID-19 accelerated change for the sector, the changes that are likely to stay, and what can be reimagined and made better. The pandemic accelerated the adoption of practices, new ways of living and working, and technologies that were expected to take years to develop.

Amid the tragic consequences of COVID-19, life sciences and medtech companies emerged as lights in the darkness. Decades of scientific work and investment seemed to be overnight successes. The heroic dedication of health care providers was met by the fastest novel vaccine development in history, and traditional competitors partnered to accelerate research and manufacturing.

Redesigning work, workplace, and workforce while meeting individual needs—

Almost overnight, our ways of working and living changed and are in a continuous state of reimagination; flexibility is more important than ever. Lessons learned from the pandemic bring sharp focus to global human capital trends that have been evolving for years—trends toward well-being, reskilling, and *superteams* (humans working with machines). Companies have the opportunity to reassess what work means and to reimagine how it's done.

2020 also saw exponential growth in connectivity through greater use of digital tools, faster (5G) networks, and cloud computing. New ways of collaborating reduce the time, distance, and cost of communications. Deals are often consummated remotely. Companies are also reevaluating the need and role of work campuses, looking for new ways to maintain culture and drive innovation.

And as new ways of working can tax mental and physical health, life sciences and medtech companies are expanding mental health resources and promoting well-being. Behavioral health needs of workers will be critical to helping them thrive—and for acquiring new talent.

In the future, it is essential to find ways to keep the workforce feeling emotionally connected no matter how or where they work. One of the biggest challenges for life sciences and medtech companies will be fostering a sense of belonging among employees and ensuring that innovation is not lost in a purely virtual environment by deploying better remote collaboration and tools.

Accelerated digitization: New points of care, new roles for pharma and medtech—

One of the effects of the pandemic was the rapid adoption of virtual care, which enables sharing of data and insights across the complete circle of care—from disease prevention to treatment to monitoring. This shift in health care delivery is likely to provide a better understanding of the role and effectiveness of pharmacology in treatment.

However, tracking of quality measures for virtual health and training physicians in web-side manner remains challenging. These quality measures are critical to pharmaceutical companies and for building data on health improvement and outcomes. Eased regulations during the pandemic increased adoption of telemedicine in many countries, but reimbursement and regulatory policies postpandemic will be key to permanent uptake and growth. While eased regulations in some countries such as the United States, Canada, China, and Singapore are likely to remain, more work is needed in other countries.

New digital health initiatives have the support and funding of governments, and tech companies are playing a major role in helping the move toward digital-first. The home is a hub of connectivity and emerging as a clinical point-of-care. Home testing and point-of-care testing are undergoing a revolution, and medtech companies can expect continued competition from consumer tech.

During the pandemic, startups and incumbents expanded home delivery of medicines, even drone delivery. Other consumer companies are bolstering health care services—digital pharmacies are adding telemedicine, and retail pharmacies are creating super health care centers. Pharmacies are administering COVID-19 vaccines, and in the future, the pharmacist may be a recognized care provider, prescribing acute medications and managing chronic diseases.

New customer-centric commercial model: Meeting physicians where they are, on their terms, and through more meaningful interactions—When hospitals and doctors' offices barred in-person sales visits to minimize virus spread, virtual visits with sales reps soared. Today, some doctors say they will stick to video calls with reps, but others miss in-person visits. A hybrid, more supportive, commercial model is evolving that is a mix of both.

Reps who succeed in future will be those who understand the science, who are interested in patients, and who are capable of having meaningful discussions with health care professionals (HCPs). The post-COVID-19 opportunity is for the industry to rethink how to engage with physicians and how to drive value through digital channels and

products on demand. Sales and medical affairs teams can benefit from coaching in empathy and virtual interactions. The mega medical congresses of the past are expected to make way for more virtual, focused, and hybrid physical/digital events.

New types of collaborations and clinical trials reshaping research and development—Accelerated digital transformation during the pandemic saw agile teams, speed to market, release of the minimum viable product, and senior management aligned with the process changes required for increased speed to market. The rapid development of novel vaccines for COVID-19 demonstrates that a new type of streamlining and efficiency is indeed possible. Biopharma companies are adopting various strategies for innovating clinical trials to shorten timelines, including new trial designs and new technologies such as artificial intelligence.

New collaborations with academia, biotech, platform companies, and data providers were already happening before COVID-19, but the pandemic accelerated time, attention, and capital to these types of collaborations by the sector.

Trial design and execution have also undergone changes. Pandemic trials have proven that big studies need not necessarily be multiyear affairs. Regulators are becoming more flexible about clinical trial design and the speed of trials. With support from regulatory bodies, there is a trend toward more decentralized, patient-centric trials in the long term, and they offer many advantages. More trials will be hybrid trials going forward, a combination of in-person and virtual visits.

Planning and resources are key to the success of these new models, especially to address the needs of the vulnerable or marginalized populations.

Biopharma companies should work collaboratively and transparently within the health care ecosystem and with data startups to unlock the data necessary to inform transformative approaches.

Shortening development and review timelines, thinking more like a regulator—

As the pandemic progressed, the US Food & Drug Administration (FDA) reviewed over 2,300 emergency use authorization (EUA) requests and provided EUAs to more than 600 products, enabling therapies to be available to patients faster. The European Medicines Agency (EMA) uses the rolling review for vaccines, one of their expedited regulatory tools for emergencies that also includes rapid scientific advice, accelerated marketing authorizations, and compassionate use programs. Developers were allowed to use platforms approved in other areas, such as mRNA, for new development, provided they had the data to support it.

Vaccines forced a global population health perspective, and the approach has been very collaborative between regulatory agencies and industry. Cross-agency scientific resources enabled shorter review timelines for COVID-19 drugs and treatments.

With the desire to shorten new drug development and review timelines, regulators are expected to feel the added pressure starting in 2021. Novel strategies and technologies, including real-world evidence, platform trials, remote clinical trial monitoring, and advanced analytics can help organizations succeed in the new regulatory environment, compress timelines, and accelerate insights. Also, run-on clinical trials may be here to stay, but compliance with good manufacturing

processes (GMP), which had been relaxed during the pandemic, may return.

Regulators take a risk-based approach in everything they do and thinking like a regulator is key. The best way to understand what a regulator wants is to study inspections and processes from the regulator's perspective, analyzing risks and benefits carefully. COVID-19 EUAs could be a great tool for assessing how the FDA thinks, even if a specific product is not in a company's space. Stakeholders should review the FDA's Investigations Operations Manual, updated in 2020.

Cross-border reliance intensifies the need for supply chain visibility and reshoring options—

COVID-19 shined a light on cross-border reliance—in trade, manufacturing, and distribution. Currently, over 80% of pharmaceutical ingredients come from India and China, and the United States is increasingly relying on China and India for active pharmaceutical ingredients (APIs). To decrease foreign dependencies, there is a growing trend for bringing production back onshore, or reshoring. In 2021, a significant amount of investment is expected to continue in reshoring, especially for capacity shortfalls.

Because of the urgency of the COVID-19 pandemic, manufacturing for the COVID-19 vaccine was done at risk, i.e., before it is known whether the vaccine works or not. It is unclear whether this paradigm, or any part of it, could carry forward without these extraordinary circumstances and funding guarantees. Competitors are collaborating to boost vaccine demands amid supply constraints, and changes in manufacturing and supply chain are driving the need for new partnerships. Companies should collaborate with others to ensure the consistent delivery of product into the market.

The success of the Pfizer-BioNTech and Moderna mRNA-based COVID-19 vaccines is paving the way for more innovation to come. If mRNA can be used, not just for vaccines, but for cancer cells, it may be one of the most exciting therapies since the polio vaccine. Viral vector and mRNA medicines are hard to manufacture, and manufacturing processes need to improve. A lot of pharma companies will need to leverage their partners instead of manufacturing the products themselves.

Advancing humanity: Environment, social, and governance (ESG) imperatives—Being a

good corporate citizen is about leading with *purpose*, and the impacts a company's operations have as a whole on ESG concerns. The pandemic made household names of life sciences companies, large and small, and some of these companies are now among the top 20 fastest-growing brands. With the sector on its front foot, how can companies build more trust and drive more growth for good?

In the midst of a crisis, priorities typically shift. But research shows that COVID-19 has not made people any less concerned about global climate change. Major companies continue to make pledges to reduce or eliminate their carbon

footprints. The best way to reach and maintain sustainability may be a collective, timely, and strategic focus on our human and societal values.

When it comes to equity, the pandemic has exposed many inequities in our systems, our human frailties, but also, our collective strengths. The sector's focus for 2021 should be on access, reach, and equity for all. Health equity requires meeting people where they are with the necessary resources to maintain or improve health outcomes. Diverse patients account for less than 10% of patients enrolled in clinical trials. It is important that a study population is representative of the population that may ultimately use a drug or therapeutic.

Life sciences companies are stepping up, allocating significant investments to reduce inequities in health, employment, and gender. These initiatives go beyond philanthropy and aim to accelerate meaningful change and demonstrable results. The private sector has a critical role to play in addressing ESG needs. Success today and in the future will depend on creating collective value for all stakeholders in a way that is transparent and sustainable.

To read the full report, visit:

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