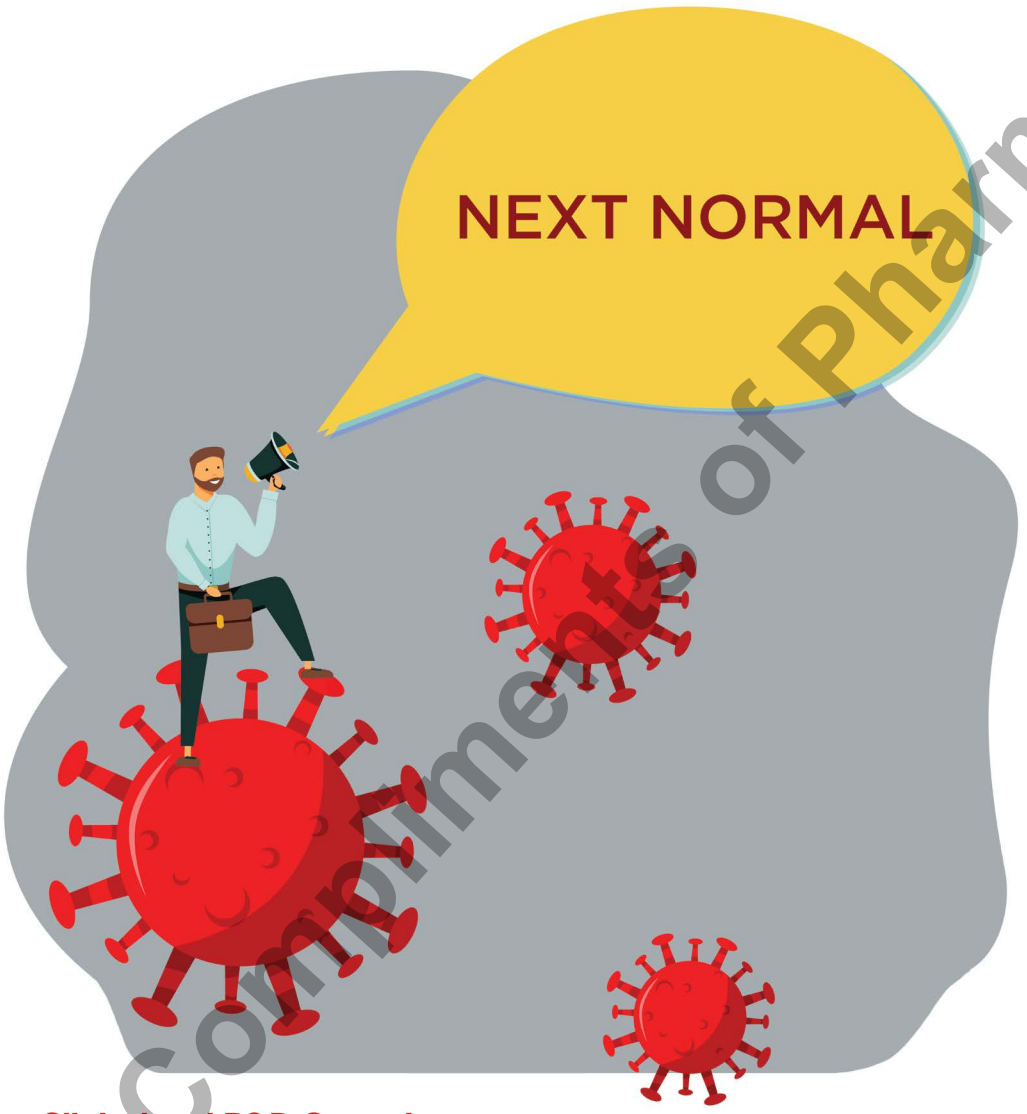
By Carolyn Gretton
and Robin Robinson

What's Next Post-COVID-19: The Next Normal



From R&D to commercial operations, stakeholders across the healthcare ecosystem are adjusting to the next phase of the pandemic: business in a new reality.

With some experts predicting that the "normalization" of business operations could be several months to a year away as the world awaits a vaccine or vaccines, organizations across the life-sciences industry are finding new paths forward as they adjust their operations to keep the engines running and the lights on. Virtual and digital are the new "in-person" connection. The pandemic has pushed companies to ramp up pilot programs and take a new look at risk- reward ratios. The world has changed and how much of this change will stick in the years or decades ahead depends on the willingness of company leaders to forge ahead into a future that is anything but business as usual.

Clinical and R&D Operations

Pharma R&D is playing a central role in the rapidly evolving COVID-19 pandemic. The industry is working double time to develop tests and treatments for COVID-19, as well as vaccines against SARS-CoV-2, the virus that causes COVID-19.

In parallel, companies are collaborating at an unprecedented rate in their efforts to thwart the pandemic. At the same time, companies seek to continue to advance their own non-COVID-related pipelines, which contain needed therapies for those suffering from other health issues, all while ensuring drug supply and protecting employee well-being.

A report by Accenture, Leading with Integrity in Response to COVID-19, observes that continuing to move clinical trials forward while taking care of patients in the studies now who depend on the therapies, is vital to world health and scientific progress. The report advises the industry to take this oppor-

tunity to "transform clinical trials and leverage the power of data and analytics at scale to improve how trials are run."

Sy Pretorius, MBChB, executive VP, chief medical and scientific officer for Parexel, says the pandemic has shone a very visible and public spotlight on the urgent need for faster and more efficient drug development.

"I interact with many people outside of industry, and they don't understand why it is taking so long," he continues. "I think the general public is understandably not aware of how complex the process is and how long it takes. In the industry, we have known for a long time that we have a challenge, and I think it's now very visible to the general public globally."

The questions become what could the industry do differently? What should it do differently? "I think personally, and we feel very strongly about this at Parexel, that we need to leverage all available data," Dr. Pretorius says. "This means data from randomized controlled clinical trials as well as from real-world sources. And, where possible, we need to integrate ongoing randomized clinical trials data with real-world sources. In other words, we really need to learn from every available patient and every available data point as quickly as possible. That way we'll obtain answers in real time."

Dr. Pretorius cites the example of Parexel having recently launched its #KeepingPatientsFirst integrated research platform powered by Microsoft Azure with other industry collaborators. "The idea in this time of the pandemic is to integrate great data from all these various sources on a real-time basis," he says. "And not only integrated in a way that can help us make faster decisions about whether the drugs are working or not, but also in a way that provides feedback to treating physicians, and to patients to help inform their decisions."

Ed Ikeguchi, M.D., CEO of AiCure, says he's seen quite a transformation over time in pharma's willingness to embrace technology as a means to improve efficiency and the way research is conducted.

"I think that's a really key foundation as we think through what really is next for pharma in terms of where they go with research in the face of COVID," Dr. Ikeguchi says. "I think it's safe to say research will continue on, unlike other industries where things have come to a grinding halt.

"Given COVID itself, there's really an intense focus now on what can be done to speed up research and make it even more effective so that companies can get some of these treatments and vaccines to market even faster," he adds. "In that regard, I think pharma companies are looking ever more closely at technology and how they can leverage technology to not just continue what they do, but to make it even better."

> When we move out of the pandemic, the world has to be prepared.
>
> **SAGAR ANISINGARAJU**
> Saama Technologies

Sagar Anisingaraju, chief strategy officer at Saama Technologies, believes there is going to be "a data explosion" at clinical sites, and that management of this data will need to change.

"We expect demands to access data will increase, and virtual trends of course will add up," he says. "What I mean by data explosion is that both medical personnel as well as clinical data managers will expect and require different paradigms and tools to gain new insights from all these new datasets. Unless technology changes are integrated into the workflows, the conventional process cannot handle the demand. There will be some element of a change management necessary because of the way in which some clinical trials are being conducted, how workflows are set up, and how handovers are taking place. A simple example: source data verification from a risk management perspective is going to completely change. We cannot use an agile process for 100% source data verification in this pandemic situation. Some of the sites may not even be properly accessible, so a more intelligent, on-demand real-time type of virtual verification of data assets will be required. This also means that conventional processes and expectations need to change. So, there will be a data explosion on one side, and change management related to how to adapt processes on the other side."

Decentralizing Clinical Trials

Dr. Pretorius says on the glass-half-full side, the pandemic has catalyzed the rapid adoption of innovations such as decentralized clinical trials (DCTs).

"The adoption of decentralized clinical trials is where we've seen the most significant change from pre-pandemic," Dr. Pretorius says. "Currently, we have more than 90 DCTs that we have completed or are ongoing and more than 50% of our new proposals now include DCT elements such as telehealth or direct-to-patient segments. I think, both personally and as an industry, DCTs were always a good idea, but the adoption was surprisingly slow. The pandemic has forced rapid adoption as companies simply had limited other options."

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>
> **DR. SY PRETORIUS**
> Parexel

According to Dr. Pretorius, Parexel has provided about 600 clinical drug shipments, a combination of direct-to-patient shipments and shipments from sites to patients' homes. "This is being driven by the significant supply chain disruption we've seen around the globe," he says. "Patients are unable to get to sites to get their drugs and site staff can't get to sites, and drugs can't be shipped across borders with everything closed."

Dr. Pretorius says there also have been big changes in clinical research associate (CRA) visits as a result of the COVID-19 pandemic. "Pre-pandemic, fewer than 10% of our CRA visits were remote," he says. "Based on our tracking data, this number jumped to more than 60% of visits in the April-to-May time frame. Since then it's scaled back to 30%, but that's still a big change from before."

Dr. Ikeguchi says AiCure has seen an

uptick in interest in its AI technology since the pandemic, given how many trials have had to shift to remote visits. "Through video conferencing, doctors can make contact with patients. This way, even if they can't quite make it in to see the doctor, we can offer a very reliable surrogate to site visits to make sure the patient is still engaged in the study and still taking his or her medicine."

Jim Reilly, VP, Vault R&D at Veeva Systems, sees three positive changes in clinical trials emerging as a result of the pandemic. "First, organizations are moving fast to decentralize clinical research by rethinking operational processes and adopting remote and virtual ways of working; these changes will in turn improve safety, quality, compliance, and speed in the long term," Mr. Reilly says. "Also, companies are accelerating their move toward patient-centric approaches in clinical trials to increase patient participation and engagement, simplify study execution, and accelerate clinical research. Finally, speed is an organizational imperative, so organizations are adopting advanced, innovative technologies — from clinical trials to product safety to regulatory submissions — that reduce complexity and streamline processes for faster drug development."

Craig Lipset, founder, Clinical Innovation Partners, says most of the countermeasures addressing the COVID-related continuity challenges in R&D have been in monitoring and decentralizing clinical trials.

"One change has been around study monitoring, the role of the clinical research associate and our ability to use new approaches for monitoring, such as risk-based monitoring, data-driven monitoring, centralized monitoring, all of these countermeasures that can let CRAs do their work in better and smarter ways, rather than the norm of just going to the site with a predefined frequency," Mr. Lipset says.

"On the flip side, the initiatives related to decentralized clinical trials have also been an important continuity measure for study teams," he adds. "We've seen increased use of video, increased visits from home health providers and increased use of data capture that can enable patients to participate in clinical studies from home. This has also included the ability to get investigational products delivered to patients' homes, which is not a simple and straightforward task."

Mr. Lipset cautions that it would be all too easy for the industry to return to business as usual once the pandemic has passed. "This is the new normal with an asterisk, because it's not the new normal just because we've done it for the past three months, and it's not the new normal just because we may have to keep introducing these tools for the next nine months," he says. "Most of what's been done to date has been done using protocol deviations and SOP — standard operating procedure — waivers. Words like deviation and waiver both mean the change is temporary and we're going right back to the way we used to do things. So, without the right commitment and measurement, these changes don't become the new normal. The asterisk becomes the new normal if we commit to doing the hard work around instantiating these changes. We have a chance to institutionalize change because people are seeing that the perceived barriers — technical, operational, user acceptance — from the site to the patient perspective, and most importantly to the regulators, have all been shattered. Research sponsors, study teams, CRO teams need these countermeasures now more than ever."

Bill Byrom, Ph.D., VP of product strategy and innovation, at Signant Health, says having the versatility to enable assessments to be conducted from home has been important to keeping trials running through the pandemic. "It is now equally important as we design solutions for new trials that will need to be able to adapt and cope with the changing landscape,"

Companies recognize they are better off using multiple partners as opposed to putting all their eggs in one basket, especially if something happens from a COVID standpoint and the organization has to shut down.

MAHESH KARANDE
Omega Therapeutics

Steps to Advance Pipeline Treatment and Patient Care

Now: Engage, empower, and enable patient access to clinical trials.

- Leverage call centers and virtual methods to empower patients and provide information on access to clinical trials, care, and investigational therapies.
- Assess cross-functional operational disruptions, including clinical supplies and alternative treatment delivery methods.
- Balance compassionate use for non-trial-eligible patients or discontinued patients with safety considerations.
- Apply Health Authority guidance for consistent clinical trial implementation to maintain safety, good clinical practice (GCP) compliance, and trial integrity.

Near term: Rationalize clinical trial priorities and lean on virtual.

- Redefine clinical trial prioritization based on unmet patient need, study progress, supplies availability, and business objectives.
- Rationalize portfolio and reallocate resources, respecting balance of trial sites' bandwidth against portfolio demands.
- Assess protocols for utility and feasibility of quick win remote capabilities (risk-based and remote patient monitoring) for safety and other assessments.
- Conduct assessment of capabilities for analytics-driven study management at scale.

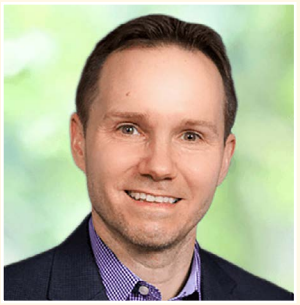
Next: Rethink the clinical trial experience and accelerate scale.

- Reimagine the clinical trial experience by proactively co-creating the trial design with patients.
- Scale digital capabilities for remote-enabled trials to build resiliency into operations and care continuity.
- Prioritize creating full-scale digital capabilities to speed time to insights for decision making and drastically reduce site burden.
- Re-examine where you hold your clinical trials and the selection of alliance sites and service providers.

Source: Accenture, Leading with Integrity in Response to Covid-19.

Given COVID, there's really an intense focus now on what can be done to speed up research and make it even more effective so that companies can get some treatments and vaccines to market even faster.

DR. ED IKEGUCHI
AiCure



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CRAIG LIPSET
Clinical Innovation Partners

he says. "It's apparent that the needs in the clinical research industry are continuing to evolve, so our mindset and readiness to adapt our thinking and technologies needs to follow suit. As we grow accustomed to the new normal, we need to continue making strides toward granting patients control of their own experience, and for study designs to flex towards less on-site and more at-home assessment. The momentum has increased over the last few months, and this partnership with patients will allow them to become more involved, more engaged, and more active in their disease treatment and management, while participating in ways they feel able and willing to do."

Sites and Patient Recruitment

To Dr. Pretorius, one of the most concerning impacts on R&D has been the number of clinical trials put on hold, which will inevitably delay new, non-COVID-related therapies getting to patients. "It's understandable because sites had to prioritize care of COVID patients," he says. "During the April-May time frame, the height of the pandemic, approximately 70% of the sites that we work with at Parexel were closed for monitoring. We're down to about 50% now globally. And approximately 13% of sites globally were closed for patient visits at the site. I think we're closer to about 10% now, so it is recovering."

Medidata, a Dassault Systèmes company, is continuously monitoring the global impact of COVID-19 on clinical trials and has released monthly reports on the situation since March. According to the July 13, 2020, edition of COVID-19 and Clinical Trials: The Medidata Perspective, the impact of COVID-19 on clinical trials has begun to level off — globally, there was a 30% drop in new patients entering trials, using Oct. 31, 2019, as the baseline. This is a significant improvement over the 70% global drop recorded in April, the report says. This recovery has varied in extent and timing within geographic regions depending on their COVID-19 cases.

According to the report, countries in Europe are seeing improvement in patient enrollment, with Italy, France, and Spain all hovering around the pre-COVID-19 baseline and Germany down about 23% from its end of October baseline. The UK started to see a pickup in patient enrollment in June after a sharp decline over the last few months and a COVID-19 case rate for June per 100,000 at about 3 to 4.5 times that of the previously mentioned European countries.

In Asia, China began to recover in March in terms of patient enrollment, while India and Japan started a slow recovery in June, the Medidata report says.

Medidata also notes that the United States saw the most significant impact on new patients entering trials in April, with a small recovery in May and a continued improvement in June. However, the re-emergence of the virus in most states in late June and early July could hurt that recovery.

Keeping Regulators On Board

At the end of March 2020, the FDA issued a guidance document for conducting clinical trials during the COVID-19 crisis. The agency has continued to update the document with recommendations for how best to conduct trials in a way that maintains compliance with FDA standards. The most recent version, updated July 2, 2020, recognizes the numerous challenges presented by quarantines, site closures, travel limitations, and interruptions to the supply chain for the investigational product, and presents considerations for assuring the safety of trial participants, maintaining compliance with good clinical practices (GCPs), and minimizing risks to trial integrity.

Among those considerations, according to the FDA document, are evaluating whether it's safer to keep a patient in an ongoing clinical trial and deliver the drug directly to them, or to have them discontinue the investigational therapy; whether alternative, remote methods for safety assessments are sufficient to assure trial patient safety in the event the patient is unable to conduct on-site visits; and whether all these alternative monitoring and delivery methods adhere closely enough to trial protocols.

Dr. Pretorius says he believes regulators have done well in adapting to the COVID-19 pandemic. "I think they've tried to adapt to this as best as possible to make it easier, with some expedited review processes, especially as it relates to COVID therapies," he says. "And I think along those lines, there is certainly increased appetite here in the United States from the FDA for some of these platform designs — such as basket trials and umbrella trials, and the use of real-world data. I commend regulators for adapting, and my hope is that we'll continue along this path, and we won't go back to the way it was before."

Mr. Anisingaraju sees the FDA going through "a fundamental shift" as regulators work to speed up reaction time for COVID-19 R&D. "When we move out of the pandemic,

Having the versatility to enable assessments to be conducted from home has been important to keeping trials running through the pandemic. It is now equally important as we design solutions for new trials that will need to be able to adapt and cope with the changing landscape.

DR. BILL BYROM
Signant Health

Regulatory affairs departments have begun to see the positive business impact that AI integration can provide over the course of the past year.

RONAN BROWN
IQVIA

the world has to be prepared," he says. "There will be more electronic verifications, more AI-driven verifications. We are working with several pharma companies to build deep learning AI models that augment, maybe assimilate, and sometimes transform the clinical data manager's work. All of this needs to be validated and approved. We expect the FDA and other regulatory agencies to quickly adapt."

Joe Rymsza, VP of pharmacovigilance and regulatory technology solutions at IQVIA, agrees that digital, AI, and machine learning are profoundly impacting how the industry is tackling larger and more complex safety and regulatory workloads. "Once viewed as being unproven and high-risk, these technologies are being embraced due to the tangible value they deliver in the collection and analysis of a growing number of data sets as well as workflow automation," he says "It's clear that regulators are quickly coming to the same conclusion on the value here as well, as is evidenced in the U.S. FDA's first public data strategy meeting this past June."

Mr. Rymsza's colleague Ronan Brown, senior VP, head of integrated technology and compliance at IQVIA, says regulatory affairs departments have begun to see the positive business impact that AI integration can provide over the course of the past year. "Regulatory compliance is a moving target with more than 2,000 new or modified regulations issued just by the FDA since 1998 and many more from the more than 150 regulatory bodies around the globe," he says. "Meanwhile, data growth has exploded, exceeding what is possible for humans alone to process. AI is playing an important role in helping the pharmaceutical industry stay compliant and keep pace with changing expectations and standards. Companies will benefit from additional improved efficiencies as they move toward more fully integrated systems for regulatory information management. AI-based automation is showing great promise in safety and regulatory compliance respectively, but its potential is limited by the inability of the two departments to share information for broader data visibility and more actionable insights. The next step toward reaching the full potential of AI integration will require the breakdown of informational silos via fully interoperable technology platforms."

Where the Money is Going

Mahesh Karande, president and CEO of Omega Therapeutics, says he's seen the overall pharma value chain become more robust in terms of more communications and collaboration.

"Companies realized they are better off spreading their clinical trials around as opposed to holding massive recruitment projects in one center or another," he adds. "Companies also recognized they are better off using multiple partners as opposed to putting all their eggs in one basket, especially if something happens from a COVID standpoint and the company has to shut down."

According to Bain Capital, one of the effects of the COVID-19 crisis on the broader pharma environment has included reduced funding for early-stage biotech companies and diminished demand for CROs.

Dr. Pretorius says putting clinical trials on hold has had an impact on the financial stability of clinical sites — especially small, dedicated research sites — around the world.

Mr. Karande says a lot of smaller companies, especially the ones in the later stages of clinical development, were distressed by the COVID-19 pandemic.

"There are some companies raising private money that suddenly found themselves materially affected because they were in the clinical trial stage," he says.

Still, Mr. Karande observes that biotech indices are at a record high, with a number of companies going public every week.

"There's still tremendous liquidity in the market for biotechs, and what that means is there's public money coming in," he says. "This means there's enough funding for R&D projects. Now, even if something untoward happens next year, money's already flown in."

Mr. Karande says he sees a very healthy biotech sector with a lot of R&D work going forward.

"I also see bigger pharmaceutical companies creating more earlier-stage collaborations than they would have done before," he says. "I think they are realizing it might not be a bad time to outsource research or tap into regional research that biotechs are doing, because there's a lot of innovative research happening. This is also a positive force toward R&D, at least earlier-stage R&D."

The Post-COVID R&D World

According to Mr. Reilly, the industry is starting to get operations back on track and restart trials that are months behind, and R&D is transitioning from largely manual operations to virtual and digital processes.

"The industry has adopted many changes

to ensure continuity during COVID that will have long-lasting impact," he says. "Clinical trials will become hybrid, where patient care is split between the site and the home. Clinical studies will be connected virtually across sponsors, CROs, and sites for better collaboration and execution. And regulatory, quality, and safety will become more digitized and automated to maintain compliance and drive more efficient safety reporting."

Dr. Pretorius believes the pandemic has raised the profile of clinical trials across a broad spectrum of the population.

"One interesting thing is for all of the bad things associated with the pandemic, it has really increased general public awareness of clinical trials and the importance of clinical trials," he says. "We did a monthly survey to gauge patient perception over a three-month period with some of our vendors, asking the question: 'how willing are you to participate in clinical trials?' In March, about 50% of the respondents said they were willing; in the two subsequent months the response went up to 60%, then more than 70%. Clearly the pandemic has shone a spotlight on the importance for us as a society to participate in clinical trials. Without public participation, we won't get treatments. We won't get therapies."

Dr. Ikeguchi predicts that R&D "is going to march on as strong as ever," although maybe not in as accelerated a fashion as it is now. "COVID has been a wake-up call for many; there's no better way to infuse efficiency into the system than a good old pandemic," he says. "And, we may find that out of a need, the pharma industry will adopt a number of methodologies that just make more sense from an efficiency perspective through technology. With COVID or without COVID, I think we're going to find a very robust industry in terms of efficiency."

He notes, however, that this is not the first attempt at improving efficiency through technology.

"With EDC, we tried to get rid of paper to build greater efficiency, and now we're seeing remote processes," Dr. Ikeguchi says. "And R&D, while it's been a bit behind the curve, is following along."

He says there is a general understanding that if people can receive their pills through the mail, if they can make contact with their physicians through their computer, if they can see their lab results through a portal, there is no reason why either as a physician, an investigator, or a patient they can't participate in a clinical trial enhanced by technology. "We're going to see this really start to take shape — again, with or without COVID," Dr. Ikeguchi says. "Coming out the other end of this, we'll end up with an industry that's a lot more robust."

Reuters Events and EY recently partnered on a survey of about 800 executives across pharma, biotech, and med-tech with three core objectives: identify underlying drivers of change, determine how pharma is being redefined, and explore what it means for pharma's future model.

According to the Reuters' study, from a clinical trials perspective, 43.5% agree that sites have enabled and supported a speedy transition to digital trials, and 72.9% believe COVID-19 drove digital adoption that can boost long-term cost efficiencies in clinical trials.

Also, 61% expect to see a significant increase in the number of wearables and other remote capture devices for data collection used in trials in the next 18 months.

"One of the findings is that organizations are moving to be digital first and innovating in R&D," says Izzy Gladstone, VP marketing, pharma, Reuters Events.

But she says R&D is lagging behind the commercial side of the business. "When we looked at commercial changes and R&D changes, it appears that R&D has adapted slowly when compared with their commercial colleagues who are literally having to deal with the fact that they can't get access to HCPs anymore," Ms. Gladstone says. "But that said, conversely, we believe the results show that R&D organizations are still most likely to commit toward long-term change. However, most leaders on the commercial side expect some levels of normality after 18 months or so."

Commercial Operations

As the industry looks toward what next steps need to be taken to effectively commercialize products during and post-COVID-19, one thing becomes clear: digital health, which has been inching its way toward broader adoption, is about to boom. From pharma marketing and sales strategies to physician telehealth visits, technology in this space is evolving and being adopted at unprecedented rates.

According to a recent report from Reuters Events & EY, it is a safe bet to predict an increased use of digital in the post-COVID pharma landscape. The report, Beyond COVID-19: Pharma Reimagined, states that an overwhelming majority — 85.2% — of respondents anticipate higher levels of investment into digital over the next six to 12 months due to the pandemic, with many more — 82.8% — anticipating sustained investment over 24 months.

Big questions still remain however: how big will this transition be? Will this usher in the long-anticipated age of digital health? If so, what will pharma's role be?

Our experts on the commercial side of the pharma business examine the impact the pandemic has had and will continue to have on the industry, from sales and marketing strategies to increasing use of telehealth and technology. Many believe that COVID has only accelerated trends that were happening slowly anyway.

"A majority of companies are taking a hard look at budgeting in and around telehealth in a marketing sense and the skill sets and capabilities of their salesforces," says Karen Young, leader, PwC's Health Research Institute.

The healthcare market will no longer reward incremental innovation; it will reward increased value and the reduction of cost.

IZZY GLADSTONE
Reuters Events

Companies will need to focus on having the right trained talent for the digital health world and be sure they are equipped to engage with physicians in this way.

KAREN YOUNG
PwC's Health Research Institute (HRI)

All promotional and marketing channels need to be reevaluated. Marketers need to take a step back and look at what the new patient journey consists of.

MARK PAPPAS
CMI/Compas

Companies need to prepare for a more digitally-centered playing field, which requires being agile and having a workforce that can accommodate the transformation. Companies may want to consider what their digital up-skilling needs are, what platforms will be adequate, and what partnerships and collaborations can help them become more agile.

"The world of technology will continue to evolve, so companies have to build agility into their organization and the operating model in order to continue to iterate and innovate long term," Ms. Young says.

Ankit Vahia, Ph.D., executive strategy director, pharma, health, and Wellness, at Grey, says one could argue that technology has encouraged more efficiency — and that we are switching to a truly global model. "With everyone working online, commercial teams are working together more efficiently and with higher productivity," he says. "The new normal of a forced virtual situation is fast tracking adaptation and evolution of the globally driven commercial strategy model — a change long sought by pharma. If anything, the new way of working supports the global-first approach."

HCP Interactions

Throughout the global pandemic, people with both chronic and acute healthcare concerns still need to see their doctors. However, many people are postponing appointments out of fear of contracting the virus. This had led to a shift in budgets from in-office to more digital initiatives. For many brand managers this was the first time they had to leverage digital tactics without the assistance from the field force. Mark Pappas, senior VP, growth and innovation, at CMI/Compas, says brand marketers need to step up and innovate out of necessity as channels continue to shift. "With salesforces sidelined, digital channels have not only become more valuable than ever but also more scrutinized by leadership at pharma companies," he says. "Many in senior leadership positions at pharma companies rely on what they are seeing from the salesforce but have realized their digital front doors were not ready or as open as they thought. While we help to future-proof many of our clients' brands by launching innovative tactics such as connected TV, telehealth campaigns, custom voice skills, and one-to-one targeted physician programmatic media campaigns, changes still had to be made. From our data we know what patients and physicians are looking for and the messaging that works and we have been able to continue to leverage that messaging and update on the fly as needed across channels."

He says all promotional and marketing channels need to be reevaluated. "Marketers need to take a step back and look at what the new patient journey consists of," Mr. Pappas adds. "For example, there may have been large geo-targeted or even nationwide out-of-home (OOH) campaigns under way to promote a brand. Now for most people the OOH bubble is a short 5-10 mile radius to the grocery store. As another example, many people are spending their time binging on Netflix, which isn't ad-supported. A good way to address this is via a connected TV campaign that leverages all digital devices in a targeted household and ties in with social media campaigns. This way the brand will be meeting people where they are. As a brand manager you can reach the people you want — patients, caregivers and HCPs alike — while they are watching TV or scrolling through their social accounts. People are on social more than ever, even HCPs, and engaging based on the content they're consuming."

In terms of pharma sales, the pandemic has changed things greatly, but with those changes also come opportunities.

According to Ms. Gladstone, the results from the Beyond COVID-19: Pharma Reimagined report, show most respondents (69.5%) anticipate HCPs will prefer fewer to no face-to-face interactions post-COVID-19. An overwhelming majority (81%) expect face-to-face access to HCPs will become more difficult post-COVID-19. This has of course been an underlying trend for years, but while the extent of change is still unclear, most (69.5%) anticipate HCPs will prefer fewer to no face-to-face interactions post-COVID-19.

Remote engagement is having a positive impact and will remain one of the opportunities that companies can capitalize on. Remote meetings are lasting longer and are more in-depth compared with in-person visits; doctors are less distracted in a virtual meeting than they normally would be in the office. So remote engagement is proving to be a more productive and efficient use of time, especially for doctors. There will be opportunities for both face-to-face and virtual meetings moving forward, but remote selling will become a much bigger part of a rep's engagement strategy, according to Paul Shawah, senior VP of commercial strategy at Veeva.

"The industry has become more virtual, and companies are finding new ways of working remotely so field reps can help physicians maintain continuity in patient care," Mr. Shawah says. "For many reps, leveraging digital to complement their existing ways of working will require a different mindset. Not only are reps thinking differently about their overall engagement strategies, but organizations are reassessing the types of training needed for reps to engage customers remotely."

COVID-19 is understandably keeping sales reps out of physicians' office, and more reps are using digital to reach them. But what will they do when offices open up again?

Experts agree that email is not going to be efficient. It's got to be through a platform. It has to be digestible. And it's got to be a one-on-one relationship that works best for the physician, what supports them the best, and what meets their needs.

Dr. Vahia says overall, sales teams will need to be armed with increasingly robust contingency plans and will need to have the infrastructure in place for virtual visits with their physicians. "The virtual approach isn't going away anytime soon, and there are benefits — less travel time, more flexibility, and the ability to meet more customers on a daily basis," he says. "At this point, the adjustment has been rapid, and all players have adapted quickly, identifying the benefits of virtual interaction and evolving practices."

According to Ms. Young, field teams will need to pivot and begin training on digital platforms, virtual relationship building, and digital communication forums, as well as

enlist remote territory management strategies to better enable the fieldforce in a remote environment. Companies will need to focus on having the right trained talent for a digital health world and equip them to engage with physicians in this way.

"There's a big surge on getting the right infrastructure and processes in place," Ms. Young says. "Companies are focused on getting the right talent trained using digital tools."

According to the Reuters Events report, remote detailing, e-meetings, webinars, and email have emerged as the most effective channels, yet there is a sense that these capabilities are still in their infancy. For example, many companies (67.6%) need a more agile method to ingest and consolidate insights across channels. "Customer interaction is clearly far from optimized," Ms. Gladstone says.

The use of digital channels will complement in-person visits in a much bigger way moving forward, Mr. Shawah says. "But it's the rep's relationship with HCPs that will lead to more digital opportunities."

These relationships will accelerate organizations' move to digital to keep doctors informed and deliver a wide array of services such as remote sampling, remote medical inquiry management, and remote consent. With this newfound flexibility to engage customers on their terms, the industry is entering its greatest era of effectiveness and efficiency in serving its many customers.

Since HCPs are now being inundated with information from sales reps across digital platforms, orchestration of processes across commercial teams becomes paramount, says AJ Polszay, Ph.D., VP of digital strategy, IQVIA Technologies. As commercial pharma teams strategize about how to extract the most value from new technology investments and processes, those focused on fine-tuning their approach to HCP engagements will be the best equipped for success following the pandemic.

"Digital adoption may have happened overnight because of COVID-19, but it remains far from optimized," Mr. Polszay says. "Looking beyond the pandemic, coordinating commercial activities will ultimately enable delivery of a more exceptional customer experience with a bigger business impact."

Orchestrating all commercial activities across the enterprise and leveraging the resulting insights to tailor HCP engagement will be more important than ever post-COVID. This means understanding the specific workflow within life-sciences companies to enable internal teams to connect across silos to deliver the best experience to customers. The average virtual engagement between pharma sales reps and HCPs lasts only 14 minutes, according to research from IQVIA. With more content flowing across fewer channels, only the most relevant message on the appropriate channel at the right time will have an impact.

Now is the time to revamp commercial go-to-market models, as organizations prepare for a more digital and virtual future, Ms. Young suggests. "Organizations have a really big opportunity right now to take a step back to re-imagine what the future looks like in a

Marketers must be nimble and strategic, while still continuing to prioritize what they have always prioritized: targeted and effective communication with HCPs and patients.

SARAH CALDWELL
Veeva

Supporting Physicians Through COVID-19

DANIEL FITZGERALD
CEO and President Apollo, a Saroras company

Pharma companies can support physicians during COVID-19 by engaging more intimately, and listening, understanding, and recognizing physicians' new normal. Doing so effectively will enable physician access to needed patient care and treatments and ensure the physician's voice is being heard.

Between January and July 2020, InCrowd performed 10 waves of COVID-19 physician research, two among high-need U.S. patients, two with nurses, and one with pharmacists. In quantifying U.S. physician perceptions, the reports explored the healthcare system's readiness for the pandemic, mitigation strategies, doctors' sentiment on reopening, physician health and wellness, promising vaccines, and predictions for the future.

- Just one-third of frontline COVID-19 treating physicians plan on engaging with pharma sales reps virtually during the summer.
- Only 34% of physicians said they are willing to consider an in-person meeting during the summer, with another 30% planning to wait until 2021.
- Nearly half of respondents (48%) shared their belief that normalcy could not be achieved again without a vaccine.

Some physicians reported they felt comfortable seeing reps in-person as long as they are wearing masks and socially distanced. However, because reps travel to different areas, the majority of physicians preferred to avoid allowing reps into their facilities.

Respondents also estimated the timeline for a return to "normal" to be October 2021 — pushed out two months longer than May's estimate of August 2021.

Digital technologies will become a more important component to companies' engagement strategies, but relationship-based selling will continue to be just as critical.

PAUL SHAWAH
Veeva

Looking beyond the pandemic, coordinating commercial activities will ultimately enable delivery of a more exceptional customer experience with a bigger business impact.

AJ PLOSZAY
IQVIA

purely virtual way, and some companies might come up with a hybrid model, but going back to a traditional boots-on-the-ground salesforce with samples in the car will not come back for most drug categories," she says. "Perhaps some specialty drugs that need personal attention will involve in-person communications, but in general the sales field reps post COVID will operate more virtually."

However, after reviewing results from the recent Reuters Events report, Ms. Gladstone is not sure the industry has realized this impending change. In general, respondents did not expect to see a big cut in salesforces. "The conversation has essentially centered on whether or not this is a time to improve operating margins and prepare for a probable future where current capabilities don't match customer needs," she says, and this is reflected in attitudes about the future size of the salesforce. According to Reuters Events, while most (63%) respondents think there will be permanent downsizing, they still don't expect big cuts. Just 5.3% think salesforces face a significant downsizing of 25% or more. In fact, almost half of respondents (49.6%) think there will be no change in the size of commercial teams, more than those that expect a reduction (30%). These findings are puzzling to Ms. Gladstone, as she wonders if the reps aren't meeting physicians face-to-face, and the numbers aren't cut, what will they all be doing. "Organizations with large headcounts have difficult questions to face longer term," she says. "To be clear, this doesn't need to translate into cuts. Pharma for the most part has maintained revenue and margins, buying valuable thinking time to strategize and determine what's next. Morale, culture, and existing customer relationships should be defended, and well-managed up-skilling can be vastly cheaper than hiring."

Marketing

As it relates to marketing practices, COVID-19 has pushed more communications to digital and made them increasingly addressable. As sales rep face time with HCPs has been impacted, marketing has had to play a larger role in the broader communications plans of clients. "Non-personal promotion now figures prominently in the launch of new products," says James Woodland, chief strategy and financial officer, CMI/Compas. "I think many of these changes will be here to stay, even in a post-COVID world."

The Crossix Data Platform has seen dips in marketing spend, but the majority of brands have continued to invest in their marketing efforts over the past few months. "Non-personal promotion will play a bigger role post-COVID with increased emphasis on content and the customer experience," says Sarah Caldwell, general manager, Veeva Crossix.

"When COVID first hit the United States, there was tremendous uncertainty, and we saw brand managers weigh investments based on different factors — mainly wanting to maintain awareness and the likelihood of their drug being prescribed via telehealth," she says. "Some brands changed their marketing strategy or messaging based on whether their patients had certain conditions that put them at a higher risk for COVID."

Using its SaaS platform for measuring and optimizing healthcare marketing, Veeva reported that nearly all (97%) pharmaceutical brands that advertised directly to consumers through digital channels pre-COVID-19 have continued to do so, albeit some at a reduced volume. Since the pandemic hit the United States in March, digital DTC impressions have hovered around 30% less than daily averages in February 2020.

Brands advertising to HCPs have reduced their digital presence as well, with 81% continuing to advertise through display, video, and mobile. Daily digital impressions for HCP campaigns have fluctuated over the past few months but have dropped more than 55% compared with February averages. Brands advertising on TV have also reduced their investments, with 82% of brands continuing their media buys during the pandemic.

"Marketers must be nimble and strategic, while still continuing to prioritize what they have always prioritized — targeted and effective communication with HCPs and patients," Ms. Caldwell says. "As the current climate continues to change, it is important for marketers to have a proper measurement plan in place to ensure that their communications are driving positive impact."

Dr. Vahia says the tried-and-true marketing methods don't — and won't — apply any longer. "Frankly, that is a good thing," he adds. "There is a significant shift toward digital and unbranded approaches. Moreover, by leveraging targeted data analytics, marketers are beginning to focus on a more specific and personalized strategic approach. The one-size-fits-all, top-down approach led by starting with a single promotional strategy and then applying it every scenario is starting to erode. There is an understanding that customer engagement needs to be specific and needs to continually evolve."

There are two key areas that will start gaining more importance, according to Dr. Vahia: a deeper understanding of customer behavior, and how that applies to the various customer segments. "Strategic tracking of customer

engagement habits will be an increasingly valuable strategic asset," he says. "This pandemic has generated a tremendous amount of data in regards to customer engagement and preferred resources/channel. We expect that those analytics will play a major role in the decision-making processes, as they should. In general, the old days of having a 'block-and-tackle' strategy will and should cease to exist. Now is the time to take the next step into truly personalized marketing and embrace that long-promised digital revolution."

Physicians are asking for a much broader portfolio of assets, tools, interfaces, and platforms to help support patients, not only in COVID, but in today's telehealth world in general. PwC reports that 50% of physicians polled want virtual patient-support services from pharma or its reps. "They want digital tools and information to share with patients from the commercial organizations," Ms. Young says. PwC's Health Research Institute also reports on the explosion of telehealth. The recent COVID-19 Consumer Health Survey shows that of those who had used telehealth for the first time this year, 88% said they would use it again.

Mr. Pappas says the major shifts are in content consumption. "People are seeing their doctors on their screens, going to work on their screens, and being entertained on their screens," he says. "Connected TV consumption more than doubled compared with last year. Samsung has seen streaming increase 138% across their devices. We have also seen a great appetite for digital video. According to data from Google, almost 30% of brands are planning to shift dollars to more online video — while only 8% are shifting to more TV. As patients have moved toward virtual appointments, doctors are looking for video resources to send to patients that explain things in an easy to understand way. Typically, pharma-produced videos, especially for HCPs, have been extremely technical and hard to understand for the average patient. Providing video assets and other brand materials in a digital format are key to helping patients understand their conditions and treatments and extremely helpful for HCPs to communicate with their patients. Additionally, with the advances in connected TV, it is now possible to target patients and HCPs on a one-to-one basis. With the 50+ and 65+ demos the fastest growing users of connected TVs, it is essential to have a presence there."

Experts predict that patients, for one, will never want to return to the "old normal," before virtual visits and telehealth initiatives. "Once you've experienced telehealth as a patient or a consumer, you never want to go back," Ms. Young says. "For example, my mother-in-law is 84, and it would take my husband a full day to go to her house, pick her up, take her to the doctor's office, wait for hours. Now since COVID, they participate in virtual visits. He drives to her house, dials up, has a 30-minute conversation, and they are done. This is the future we are heading toward and it is much better for all."

The old days of having a 'block-and-tackle' strategy will and should cease to exist. Now is the time to take the next step into truly personalized marketing and embrace that long-promised digital revolution

DR. ANKIT VAHIA
Grey

Next Steps

There are no easy paths ahead and pharma leaders have the unenviable task of investing today for a very uncertain tomorrow, Ms. Gladstone says. There is no one-size fits all model for the industry — leaders have to assess portfolio needs and invest accordingly. The future is undoubtedly digital, medical, and patient-focused, but the question of how much and where is very much in the air.

Now is the time for bold steps into the future, our experts say. There is no turning back the clock in order to embrace strategies and operations that are familiar. "It is time to think about the when, the where, and the how consumers and patients want to be served; how physicians want to be served; and how to use AI, analytics, and predictor tools to more effectively target," Ms. Young says. "There's a window of opportunity right now because the market is down and new behaviors are emerging, companies can conduct bold experiments with people thinking outside of the box and innovating."

The big shift of the last decade has been the transition toward value and in many ways COVID simply accelerated pre-existing trends.

COVID-19 mostly accelerated change in the industry that was already under way.

JAMES WOODLAND
CMI/Compas

"The healthcare market will no longer reward incremental innovation; it will reward increased value and the reduction of cost," Ms. Gladstone says. "The pressure will be on both pharmaceutical and digital health innovators to adjust to that expectation."

There are also clearly emergent customer needs that must be met. Digital teams have ample space to grow beyond the skeleton crew currently serving organizational needs. As added-value content becomes king, production should move in house. Strategic and medically literate capabilities are required, and patient-facing functions will grow.

"One thing is certain, transformation is coming for pharma, the only question is when," Ms. Gladstone says.

Dr. Vahia says all too often marketers look for the "next big thing" when it comes to marketing, whether it be a new technology or platform, but the most important thing for marketers will be ensuring their deep understanding of customer behavior and how it is evolving.

"When coming out of a crisis of this magnitude, it will take time for people to find their new routine and adjusted comfort zone," he says. "This will inadvertently impact their mindset and therefore their behavior. There will be new preconceived notions and behavioral biases that will creep in. As marketers we need to pay attention and ensure that we continue to engage with them not just as it applies to a specific product or brand, but in relation to their overall viewpoint. It is a fascinating time to be a marketer." PV