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A report from the
Deloitte Center for Health Solutions

Breaking barriers to digitalization in biopharma

The pandemic's impact on R&D and commercial operating models

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Executive summary

THE COVID-19 PANDEMIC has affected all aspects of life around the globe. While the biopharma industry is squarely in the public eye as it works to develop vaccines and therapeutics for the novel SARS CoV-2 virus, there are other significant areas of its businesses that have had to adapt to a changing world. We talked to leaders across a variety of commercial and R&D functions to learn how the pandemic has altered their way of working in the short term and how they predict it will affect the way they work in future. We found a mix of sentiments. Some people felt that there may be an opportunity to get back to business as usual once an efficacious vaccine has been distributed; others said that the biopharma industry is forever changed. But virtually everyone told us that the invaluable business learnings from the pandemic have accelerated changes in strategy and operations.

Interviewees agreed that it has taken organizational agility to address challenges caused by the pandemic:

- A dramatically shifted sales environment, altered launch dynamics, and the scramble to implement new digital strategies drove changes in commercial functions.
- Challenges related to running clinical trials amid a pandemic, including reallocating sites and staff as well as adopting new technologies to keep drug development on track, dominated the R&D side of the business.[1]

Most interviewees told us that they have had to think differently—about vendors, partnerships, and digital content, for example—to navigate the crisis, and that most companies—both large and small—embraced the challenge. We also saw differences in impact by therapeutic area (TA). Sales and clinical trials were harder hit in TAs such as dermatology where the unmet medical need—one that is not addressed by existing treatments—is relatively low. Oncology and rare disease, on the other hand, have continued mostly unscathed.

While biopharma companies are adapting to the pandemic, to say that it has been smooth sailing is an overstatement. Manufacturers had to make quick decisions as well as reevaluate their priorities and how they reach their customers. This was particularly challenging for companies with complex infrastructures. On the R&D front, companies have had to revisit traditional clinical trial design and patient recruitment methods.

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Commercial functions have been forced to virtualize their operations and rethink their marketing strategies.

Prior to COVID-19, manufacturers viewed digital transformation as a long-term objective; today, it is a necessity. We are seeing rapid uptake of digital technologies by the biopharma sector in order to facilitate internal and external operations, but will the momentum continue once the pandemic ends? And what will patients and customers want? The answers remain to be seen, but the biopharma industry should be prepared for drug development and sales to change in the postpandemic world.

METHODOLOGY

In fall of 2020, we conducted 14 interviews with R&D and commercial leaders at both large and small biopharma companies, as well as contract resource organizations (CROs), to understand how the pandemic has impacted clinical trials, sales and marketing, and investments. Additionally, the executives provided insights into how companies will react to challenges posed by the pandemic.

Selling drugs during an active pandemic

Despite uncertainty and operational challenges, finances are stable

For the most part, interviewees told us that companies are financially healthy, and that sales of marketed products have remained mostly steady. New drug launches may face some expected challenges with meeting forecasts, but interviewees said that revenue forecast revisions have not been necessary in the short term, nor has scenario planning for a second wave. "We aren't seeing a huge shift yet," is what one interviewee told us.

Delayed trials, for example, save money used for recruiting efforts in the short term, but those costs will be pushed to whenever the trial resumes—which most have done. However, if the pandemic lingers for the longer term, forecast revisions and adjustments to strategy might be warranted. In fact, several of our interviewees see this as an opportunity for biopharma. Those with excess cash may be looking to bolster their portfolios with external assets as their own pipelines are delayed. It may also force manufacturers to reassess their portfolios to focus on development where they have their best chances. Investments from private entities continue to flow into biopharma. But, as one interviewee said, "It will take years for us to fully understand the impact that COVID-19 has had on the industry."

Product revenues are steady—for now

While interviewees said it has been challenging to sell new drugs in 2020, they believe the overall market share for products launched before the pandemic is steady. Companies have not seen dramatic losses in revenue beyond what was expected. There are a couple of reasons for this:

- In the first three months of 2020, stockpiling of drugs by wholesalers, pharmacies, and patients resulted in a sales boost of about US$1.2 billion across eight major manufacturers.[2] This meant that companies supporting patients who were already enrolled in treatment regimens were temporarily buoyed by advance sales of drugs, even if potential new patients were not going to see their doctors for prescriptions. It also meant that companies could fend off competitive products since patients were not easily able to switch to something new. But if patients continue to postpone medical visits, the positive effects from stockpiling could wane and losses may be felt in the future.

- Many high-cost specialty drugs, particularly those in oncology or rare disease, continue to be dispensed or administered as part of critical, life-saving care. For example, while sales of Kymriah, a CAR-T therapy from Novartis, fell slightly short of analyst forecasts in the first quarter of 2020, they more than doubled between the first half of 2020 compared to the first half of 2019. This was despite a pandemic-induced pause in the provision of health care services.[3]

However, interviewees told us that they have seen a decline in the sales of some drugs that require a hospital or clinic visit for administration, including some for oncology and rare disease. Patients were either too afraid of contracting COVID-19 in the clinical setting or didn't feel that their condition was bad enough to seek treatment and risk exposure. Several interviewees told us that health care systems are expecting to see more patients with advanced disease in 2021 as a result of delayed treatment or diagnosis.

Drug launches have suffered during the pandemic

Most of the marketing leaders we spoke to told us that companies have either revised or scaled back their launch strategies as a result of the pandemic. They also said that the market response to drugs that had launched as planned this year has been lackluster. As convenings of medical professionals—from large-scale congresses to small-scale dinners and events—have been cancelled and moved to virtual formats, biopharma companies are struggling to get the word out about new products. One interviewee told us that under normal circumstances, companies would be operating at a "running speed," pursuing a variety of channels through which to release content. But since many of those channels are not options, companies are instead operating at a "walking speed." He added, "The real estate that media, both specialist and traditional, dedicates to drugs and approvals is lower. COVID-19 is the priority, so there are just not as many eyeballs on our data."

Interviewees also talked about how making the best of the one shot there is to get a launch right during a pandemic when traditional strategies can't be used is so difficult to figure out. One said, "I'm working on a launch right now and it's crazy. No one knows what we should do and not do." As highlighted in our recent article *Key factors to improve drug launches*, about 70% of products that miss expectations at launch continue doing so in subsequent years, making launch success imperative. But one interviewee told us that launch delays are not being considered since patent life must be maximized; another pointed out that delays cost the company money and that even modest revenue is better than no revenue. Therefore, any anticipated launch delays are likely due to delayed submissions stemming from issues such as stopped or slowed recruitment or missing or late data and *not* for strategic reasons. In fact, from our analysis of EvaluatePharma data, the average number of days from FDA approval to launch has increased only by 12 days for the first three quarters of 2020 compared to 2019.[4]

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Sales representatives are less influential in a virtual world

One key component of launch strategy is having field sales representatives engage with physicians in person. This is a critical communication channel between the manufacturer and the prescriber. Every interviewee told us that COVID-19 has effectively shut down these in-person channels and forced a dramatic shift in how biopharma field sales reps work. Here is why:

- **The engagement model:** Social distancing requirements and shutdowns have forced reps to engage with physicians virtually, using new and sometimes yet-unproven methods such as apps and portals rather than through the usual face-to-face interactions in offices, at congresses, and at targeted events. Influencing physicians virtually is mostly uncharted territory. Companies are looking closely at which platforms are best for delivering specific kind of content. These include anything from customer resource management tools and videoconferencing to social media platforms meant specifically for physicians. But despite significant investments in adopting or upgrading digital and virtual technologies, interviewees told us that results have been mixed. Some suggested that a split approach taking physician preferences into account—where younger, more tech-receptive physicians are engaged digitally, and others are pursued through traditional methods—may be required.
- **The audience and content:** Many physicians have been called away from their usual services to provide surge capacity on medical wards, leaving little time to focus on other things. Additionally, interviewees said that the virtual environment lends itself to physicians being distracted or half engaged as they multitask on their computers from home, for example. In order to get the attention of busy clinicians, our interviewees told us that content offered through digital channels will likely have to be more compelling and differentiated from other content. Interestingly, one interviewee told that he's seen a renewed interest in print content, likely because people are growing tired of looking at screens all day long.
- **The role:** In order to minimize contact, sales reps have not been allowed into private physician offices and academic medical centers. Charismatic, outgoing individuals are often drawn to the sales rep profession since it plays to their social skills and ability to make interpersonal connections. As one interviewee told us regarding the shift to virtual, "You hire the best pilots to fly 787s and now with the ongoing pandemic we ask them to fly helicopters. It's sort of the same thing but it's totally different." Keeping reps at bay may lead to reduced productivity and job satisfaction, especially as the pandemic continues.

"You hire the best pilots to fly 787s and now with the ongoing pandemic we ask them to fly helicopters. It's sort of the same thing but it's totally different."

MEDICAL AFFAIRS TEAMS HAVE TAKEN ON AN EXPANDED ROLE

Marketing leaders told us that due to the pandemic, physicians are consuming information through nontraditional channels and that biopharma companies are doing their best to keep up with the changing demand. Medical science liaisons (MSLs) are another key communication channel between manufacturers and physicians—possibly even more salient as sales rep engagement has decreased—since they provide scientific information about products and other topics, including COVID-19. Manufacturers are revising their communication strategies to cater to current physician interests, needs, and habits:

- **Focus on science:** As physicians have been largely cut off from interacting with colleagues at congresses, etc., interviewees pointed to an interest in scientific support from biopharma, including information about treatment patterns, when they may not have time to read journals.
- **Differentiated content:** Companies are pouring more resources into creating meaningful programming as they battle for physicians' eyes and ears. This includes speaker panels and other events on topics not limited to their own products that could draw attention and attendance. In fact, several people told us that education has become a key focus area for medical affairs teams. One interviewee noted that interest in scientific content has been growing in recent years. He said that the trajectory of this trend will vary based on therapeutic classes. However, it will be tricky for manufacturers to keep commercial activities separate from MSLs given their expanded presence.

Most of our interviewees told us they expect at least some of the changes to be permanent and that downsizing the field salesforce may be inevitable as new ways of interacting with physicians continue. And while interviewees agreed that companies are likely to leverage digital platforms more in the future, the magnitude of the resulting salesforce size reduction was up for debate. In fact, some interviewees suggested that the compromise in quality is too great to consider not going back to a more "normal," in-person model—though it will take some time to get there. Still, a few others said, it may be difficult to ignore the significant cost savings that come from reduced travel and events, even if the quality of virtual interactions is not as good. Physicians and health systems may also not be willing to go back to the old model. Notably, one interviewee pointed to what is already happening outside of the United States, where regulatory constraints have hampered sales reps' abilities to make physician visits, forcing companies to streamline the salesforce and increase their reliance on digital channels.

Developing drugs during a pandemic

Most trials experienced delays—especially those in early stages

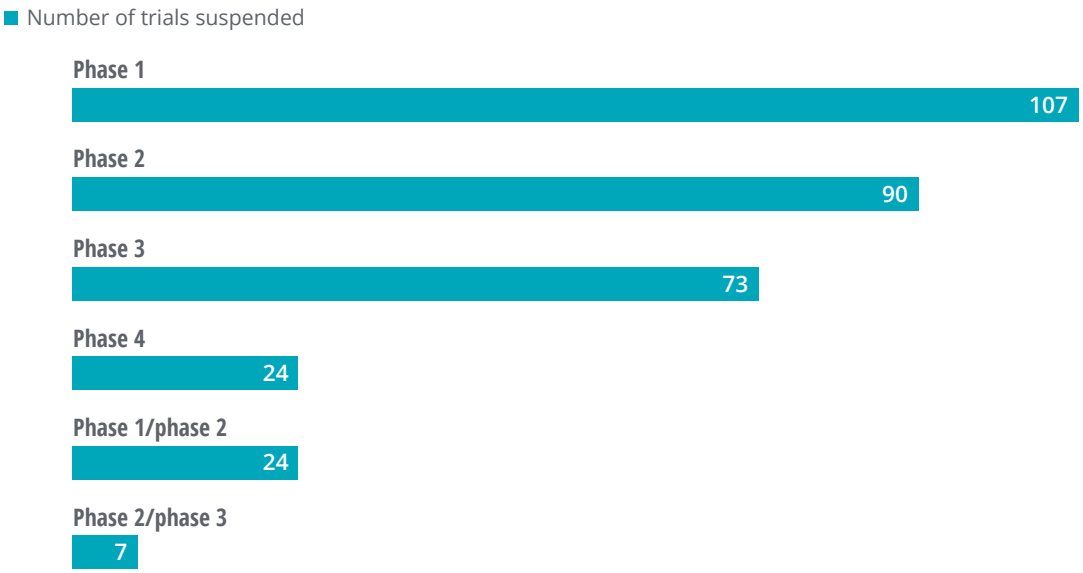
R&D leaders highlighted clinical trial suspensions or delays, especially for early-stage trials, as the pandemic's biggest impact on drug development. According to data from EvaluatePharma, many commercial trials were suspended globally between March and November 2020 (figure 1). This is primarily because:

- Study sites were forced to close due to the outbreak, or
- Patients could not be recruited to participate, including healthy volunteers who likely did not want to travel to study sites and risk virus exposure.

Approximately 60% of the suspended trials have since restarted, but several interviewees pointed out that additional shutdowns may be required as

FIGURE 1

Most clinical trials suspended are in phase 1



Notes: Data as of November 19, 2020. Data was captured from March 1 to November 19, 2020.
Source: Deloitte analysis of EvaluatePharma data.

the second wave of the pandemic takes hold globally.

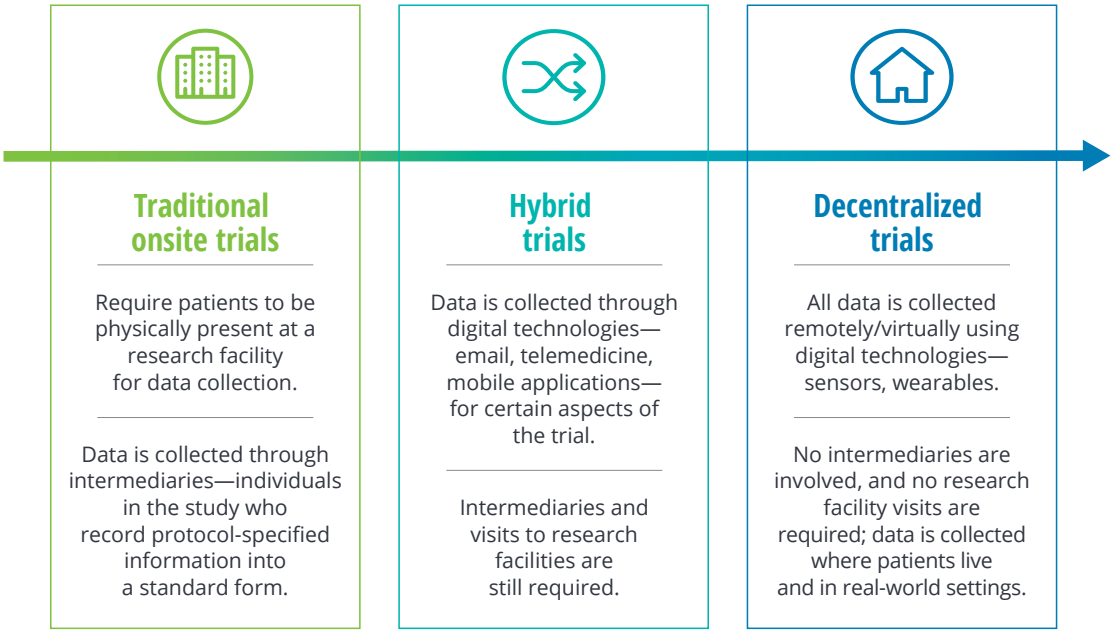
TA was one of the main determining factors for trial delays or suspensions. For example, oncology trials were less impacted compared to other TAs since they involve a higher unmet medical need and had patients who were willing to participate. Trials in TAs such as neurology or dermatology, where the benefits are more incremental compared to the current standard of care, experienced more delays and suspensions as sites closed and patients postponed or declined treatment. Interestingly, our interviewees were confident that the time lost to delays could be made up later in the development process.

Manufacturers are reallocating resources and taking risks to mitigate the effects of COVID-19 on clinical trials

The delays in ongoing trials due to the pandemic add to the overall cost of running them—whether in the short or long term—so companies want to keep them moving as much as possible. Interviewees told us that manufacturers—even large ones who had to work within their existing infrastructure—have adopted a new mindset when it comes to embracing change. We heard several examples of efforts being made to move trials from a site-based approach—which requires the physical presence of patients at the study site—toward a decentralized approach—where patients fully participate in a trial from their homes (figure 2). Most trials land somewhere in between and are

FIGURE 2

The clinical trial data collection spectrum[5]



Source: Sean Khozin and Andrea Coravos, "Decentralized trials in the age of real-world evidence and inclusivity in clinical investigations," *Clinical Pharmacology & Therapeutics* 106, no. 1 (April 2019).

labeled "hybrid." Considerations for hybrid trials include:

- **Streamlining trial activities:** This ranges from implementing e-consent forms to re-evaluating data needs and endpoints to incorporating in-home nursing.

- **Investing in or enhanced use of digital technologies:** Companies shift to remote monitoring wherever possible to keep trial data coming in.

- **Considering new partners:** Companies that may have typically chosen outsourcing vendors from a small list are expanding their view to look for different capabilities that are better suited for their specific trial and environment.

One interviewee estimated that before the COVID-19 pandemic, hybrid models comprised 10–15% of all large biopharma trials; that number has since dramatically increased to 40–50% and may stay in that range for a while even as the pandemic subsides. The interviewee told us that geographic areas of interest and feasibility based on TAs (i.e., not all therapeutics can be administered at home, for example) will be the key drivers to increasing the adoption of hybrid trials.

Both small and large manufacturers have been forced to quickly rethink their trial operations. Smaller companies tend be ahead in technology adoption and, given their size, can pivot more easily. However, they may lack resources to implement necessary changes. Larger companies may be less agile but have deeper pockets and therefore can make changes if they reach organizational consensus.

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Although interviewees are optimistic about the use of technology in clinical trials, they highlighted some barriers to adoption:

- **Embracing change:** Companies may not be comfortable continuing to use technologies such as telemedicine and may want to revert to tried and true methods of data collection once the pandemic ends.

- **Complexity and cost:** While hybrid or fully decentralized models may be more convenient for patients, they require planning and additional resources. Companies should figure out which data points and collection tools are needed, as well as how logistics will be managed. This will take time and require buy-in from organizational leadership.

Interviewees also said that maintaining and developing strong working relationships with CROs and leveraging their flexible resources

helped them counter the impact of the pandemic. They said geographic flexibility, which allowed shutdowns/restarts of trials depending upon the outbreak situation in an area, was a critical advantage. Some manufacturers had enough of a global footprint to do this on their own; others did not. CROs have been investing in digital capabilities for some time, giving them the advantage to pivot quickly to a hybrid approach. In fact, one interviewee told us that she expects to see manufacturers continue to outsource parts of their trials to CROs in the short term until they build internal capabilities for hybrid and decentralized trials.

REGULATORY BODIES HAVE HELPED SUPPORT DRUG DEVELOPMENT DURING THE COVID-19 PANDEMIC

Interviewees told us that, contrary to fears, regulatory bodies have been helpful and responsive during the pandemic for requests not related to COVID-19 vaccines and therapeutics. Interviewees cited guidance, timely response to inquiries, protocol flexibility, and remote inspections, for example. Several interviewees said that at first, they were worried about the effectiveness of virtual meetings and written responses but were pleasantly surprised. Manufacturers still wonder how issues such as missing trial data due to COVID-19 will be handled and how interactions with regulators will evolve as the pandemic subsides. Many interviewees expressed optimism and gratitude for how communications have gone thus far.

What does the future hold?

MUCH UNCERTAINTY REMAINS about the duration of the COVID-19 pandemic and the subsequent economic damage it will cause, but it has clearly accelerated many business trends that were already beginning to take shape. Social distancing and virtual work have illuminated many efficiencies that are ripe for adoption. Some of the key capabilities that manufacturers need now or in the future include:

- **Digital transformation:** In R&D, COVID-19 highlighted the frailties of the traditional, site-based clinical trial system. With support from regulatory bodies, interviewees see a shift to decentralized, patient-centric trials in the long term. In the short term, they see small-scale adoption of relevant technologies—likely through CROs or other vendors—and changes to protocols to meet immediate needs until internal capabilities are built. This could include scientific innovation (such as accelerating the use of digital biomarkers and other sophisticated measurement tools for specific TAs) as well as real-time and remote monitoring tools and diagnostics. Organizations could also use extensive data and intelligent workflow to optimize human-machine–based decision-making. Additionally, more virtual aspects to clinical trial design could significantly decrease the burden on patients and therefore facilitate higher enrollment with a more diverse patient population. As one interviewee put it, "For some, it's a hit now, but in the long term, the pandemic will turn out to be the driver that reinvents how we conduct clinical trials."

- **Commercial transformation:** Manufacturers are reconsidering their go-to-market strategies, including talent, customer engagement models, and digital tools. At the same time, they are figuring out how to differentiate and modernize their operations through digital transformation to enhance interoperability, control costs, expand existing streams of revenue, and improve customer experience. Physicians may demand entirely different communications platforms moving forward—those that take their schedules and needs into account, and provide engaging, clinically relevant content. Companies may need to rethink how to expand and better leverage the medical affairs department's expertise and capabilities.

"The pandemic will turn out to be the driver that reinvents how we conduct clinical trials."

Organizations that could quickly pivot based on changing business conditions have fared the best during this time. For some, that could mean partnering with an external entity for needed capabilities to gain a first-mover advantage; for others, it could mean making investments to build in-house solutions. Manufacturers should continue the activities accelerated by COVID-19—streamlining, virtualization, partnering—not only to shore up current operations but also to build a more agile and patient- and customer-centric organization moving forward.

Manufacturers should ask themselves:

- Where do we expect new profits to emerge and existing profits to decline? How should we rebalance our portfolios accordingly?
- Where can we drive greater efficiency in the way we operate today to build financial and operational resilience in the short term?
- Should we consider changes to our existing infrastructure and resource models to drive greater efficiencies in the long term?
- How can we better identify and access disruptive capabilities that could accelerate the path to digital or commercial transformation?
- Where should we look to partner vs. build internally? Where can we partner to help drive competitive advantage in the short term?

The pandemic has exposed long-standing inefficiencies within biopharma operating models and has become a tipping point for overdue transformation. The accelerated adoption of digital technologies in biopharma R&D could facilitate the democratization of clinical trials, making it easier for people in all geographic locations, of all races, and socioeconomic backgrounds to participate. Faster, more representative recruitment could accelerate drug development time, ultimately bringing drugs to the market sooner.

Commercial functions can use technology to better engage with both physicians and patients in ways that are more meaningful and convenient for them. Physicians may be more willing to try new products when marketed to more appropriately; among patients, better engagement might engender more trust in pharma. The knock-on effects from driving efficiencies across the organization and taking a customer-centric approach are clear—and can be a winning proposition for everyone involved.

In order to thrive, manufacturers should ensure that they are capitalizing on the momentum gained in accelerating digital transformation programs, strategic shifts, and commercial reorganization—it is imperative to remain competitive in the future and build resiliency into the operating model.

Endnotes

1. Supply chain was not a focus of this paper but our recently published article—*The first 90 days: US biopharmaceutical finished goods*—focuses on the topic.
2. Ned Pagliarulo, "Pharmas boosted by drug stockpiling, but warn of COVID-19 impact," BioPharma Dive, April 28, 2020.
3. Novartis AG, *Q2 2020 result: Investor presentation*, July 21, 2020; Etain Lavelle, "Novartis CEO says nuclear medicine, Zolgensma sales impacted by COVID-19," S&P Global, April 28, 2020.
4. Deloitte analysis of EvaluatePharma data from March 1 to November 19, 2020. Data as of November 19, 2020.
5. Sean Khozin and Andrea Coravos, "Decentralized trials in the age of real-world evidence and inclusivity in clinical investigations," *Clinical Pharmacology & Therapeutics* 106, no. 1 (2019).

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