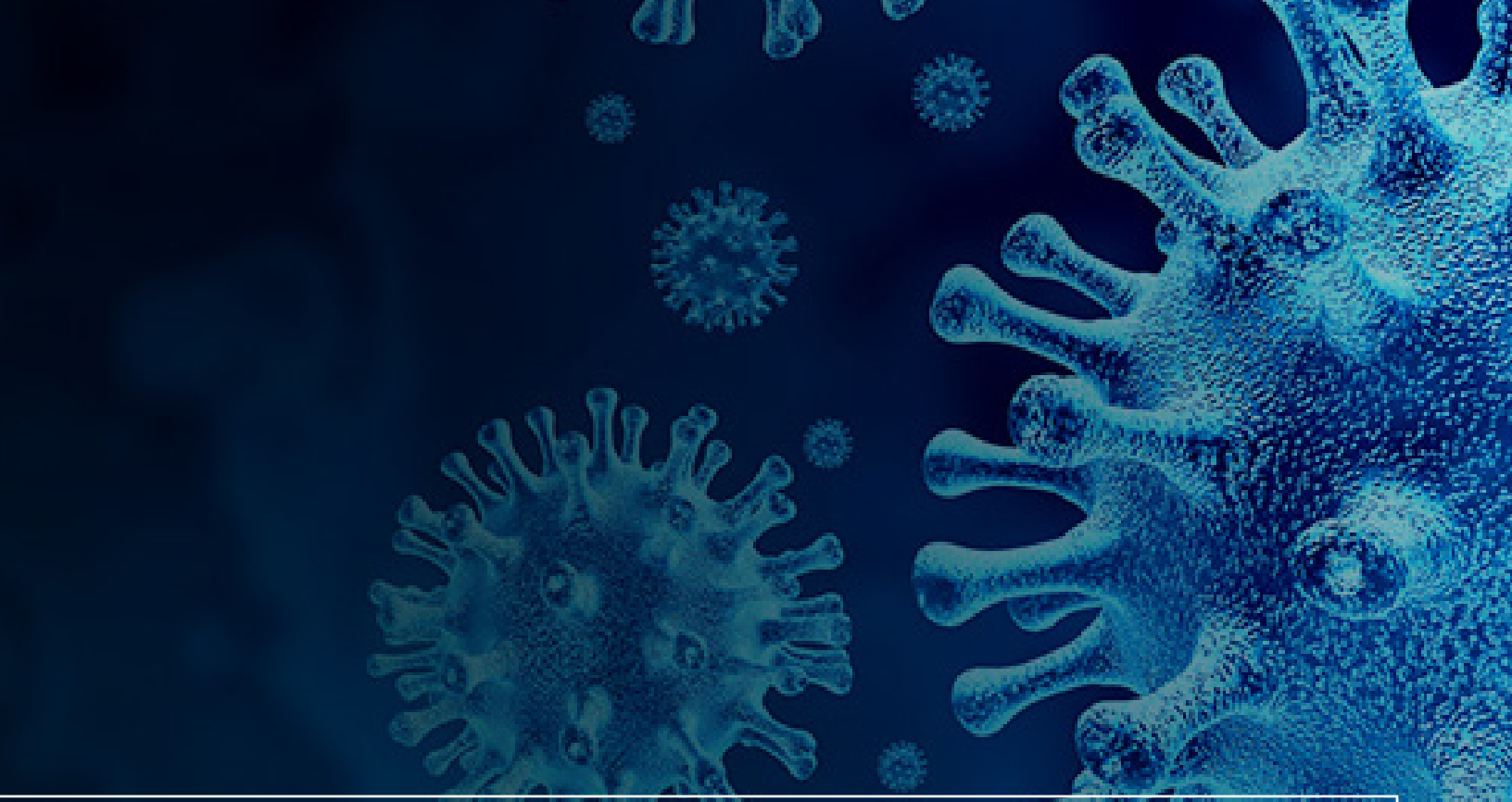

BioPharma Market Launch in the Age of COVID-19:

A Playbook for a Virtual World

Regulatory Approval Is Not the Finish Line

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Executive Summary

Transforming a biopharmacological organization to respond more effectively to emerging opportunities and challenges is difficult in the best of times – and 2020 hardly ranks as the best of times. Every CEO knows the reasons: The novel coronavirus and the worldwide COVID-19 pandemic have introduced new and unanticipated challenges in areas ranging from human resources and manufacturing processes to logistics, financing, product distribution, even clinical trial participation. It's difficult to get all the key players on the same page when you can't even get them in the same office.

Yet, the effort to move all the key players to adopt a common, holistic view of the enterprise, its processes, and its challenges and solutions remains central to the transformation that needs to occur.

In terms of addressing these challenges, one sentiment that arises from several CEOs is that there may be no better time than now because business is so broadly disrupted. There are distinct external factors that can motivate clinical, medical affairs, and commercialization teams to work together in novel ways and to learn about and appreciate aspects of the organization's mission with a new, more holistic understanding of their role in helping the organization overcome these challenges. Technology, too, can be advantageous at this juncture – not only AI but also digital health technology more broadly, from videoconferencing to actigraphy to the novel use of large data sets to complement (or potentially substitute for) traditionally captured prospective data. Some CEOs are turning to technology to build new integrated channels that can enable development and commercialization teams to interact more effectively from the earliest dates and ensure that all eyes remain fixed on a common goal, which is not, in fact, regulatory approval of a new therapeutic but the broad long-term adoption of the therapeutic after approval.

Finally, this paper concludes with a number of best-practice recommendations designed to help biopharma companies operate and evolve most effectively in the "new normal" in which they are operating. These best practices cover matters relating to:

- early and ongoing engagement with key patient populations
- the development of site-less and direct-to-patient clinical trial modalities
- the use of technologies to augment traditional launch planning processes
- the strategic rather than transactional use of partnerships to facilitate product development, approval, and commercialization

This playbook will look at the evolving challenges confronting biopharma CEOs today and share lessons learned from executives who are navigating some of these waters.

The key areas where change has disrupted the status quo include:

- financing
- travel
- in-person engagements
- relationship development

Key areas that remain unchanged (and that still require close and ongoing attention) include:

- the challenges posed by technology (AI in particular)
- the challenge of mergers and acquisitions
- the challenges posed by an evolving regulatory posture
- broad changes in the delivery and funding of health care services

Overview

The COVID-19 pandemic (C19) has complicated the transformation most life-sciences companies – generally irrespective of size and development status – have been undergoing for the past few years. It has definitely affected the pace and methods used to achieve both clinical and commercial development success. Moreover, it has trained a bright light on the reasons that CEOs have been striving to transform their organizations: The times that demand agility and flexibility, the times that require greater internal alignment and time- and cost-efficiencies, and the times that mandate the creative use of advanced technology are not abstracts associated with some distant future. These times are now.

Transforming an organization to respond more effectively to both emerging opportunities and challenges can be difficult in the best of times. Today, though, these difficulties are magnified. CEOs must harness and simultaneously accelerate the evolution that needs to take place, without compromising the needs and expectations of employees, patients, regulators, and stakeholders. C19 has made it clear that everyone involved in drug development – from the heads of clinical, commercial, legal, and medical affairs to everybody in between – must take a holistic view of both the challenges and opportunities unfolding before the company. If one looks only at the regulatory aspects of clinical development, for example, opportunities to act in ways that will optimize commercialization of a product may be missed, creating later inefficiencies that a less myopic perspective might have been able to avoid.

The question for CEOs is straightforward: How can the requisite transformations be fostered and accelerated throughout the organization? How can development teams be encouraged to embrace a commercialization mindset? Conversely, how can commercialization teams be trained to embrace a development mindset? When all teams are working together, the friction that leads to inefficiencies can be reduced.

This paper will look at lessons learned from a wide range of interactions with pharmaceutical companies during this dynamic period. C19 has altered the landscape of options when it comes to addressing many of these challenges, and this paper will explore how CEOs might respond in their own novel ways.

What has changed since the onset of the pandemic

The obvious changes include those one hears about in the news every day: Who's going into the office or the lab, and who's trying to work from home? How can employees work, interact, and communicate effectively if they're not in the office, if their children are attending school from home, and so on. These are neither trivial challenges nor are they unique to the world of bioscience. Other bright minds around the world are already trained on these issues.

The pandemic has created other challenges for pharmaceutical industry CEOs, challenges that not only affect drug development efforts that are currently underway but also those that have not even begun to take shape. Some of these changes will shape the industry for the foreseeable future, even after the pandemic is brought under control.

The dynamics of financing

The pandemic has exposed a clear weakness in the fee-for-service delivery model: higher numbers of non-COVID patients are opting not to seek care for medical issues that previously would have brought them to a care setting. Patients want to avoid going out in general and to avoid going to a hospital in particular. That has depressed revenues for many care settings and pharmaceutical companies, even as the health care system is operating at near capacity in some areas. As health care systems rethink the fee-for-service model, so must pharmaceutical companies when it comes to commercialization rollout plans.

Many large-scale pharmaceutical industry events have been canceled, and that has made it more difficult for pharmaceutical companies to raise capital – both for clinical development and for market launch:

- The Kineticos Biopharmaceutical Confidence Index (BCI), a regular survey of biopharma executives, shows that the number of executives who feel highly confident about being able to raise money in the public capital markets has dropped from 36% in November 2019 to 27% in April 2020.[1]

- During this same period, PitchBook notes that confidence among executives about their ability to raise capital in the private equity/venture capital (PE/VC) markets dropped from 47% to 28%.[2]

The pandemic has added more uncertainty to biopharmaceutical development investments, so the executive concern about capital is reasonable. However, the financial markets have not wholly reflected those concerns. Between January 2020 (pre-pandemic) and the end of August 2020, the publicly traded Biotech ETF IBB rose by more than 9%. On the PE side, though, the reality was more in line with executives' concerns: PitchBook's Q2 2020 US PE Breakdown edition notes that traditional buyout opportunities dried up during Q2, and PE firms turned to other avenues to deploy capital. PE-backed exits sank too, as firms saw markdowns in their portfolios. On the whole, fundraising has presented more of a mixed bag since the pandemic appeared in the U.S. Total capital raised remained strong because of closure of large funds, but the number of funds raised diminished as emerging firms struggled to find traction.[2]

What does this mean for CEOs looking forward? Smaller biopharma companies looking for private capital must begin to consider these issues earlier in the planning cycle and must include questions that might not, in another time, have been considered at these early stages, including patient recruitment, regulatory body availability, access to data, and an exit strategy. With investors naturally more concerned about long-term plans and investment recovery, clear contingency planning and flexibility will support investor information needs.

The dynamics of clinical development and marketing

Changes in clinical development and marketing have introduced the possibility of delivery and approval delays and, in some cases, made delays appear inevitable. There has been a notable slowing of clinical trials due to shutdowns at research sites (some of which have been geography-specific).[3-5] In some cases, there has been a shift away from traditional "research mills" and toward engagement with active medical practitioners. These individuals may have less research experience but more "real-world" experience. At the same time, the conventional model of face-to-face engagement during a study has become unsafe, if not almost impossible to continue, given the virulence of the pandemic. Clinical development teams have begun encouraging the use of telemedicine in clinical trials, and many view it as "the new normal" in the practice of medicine going forward.[6, 7]

Trial sites have tried to reopen, when and where it appears safe to do so (and when and where new safety protocols have been put into effect), if only because those in charge of the sites view clinical trials as an important source of revenue. They are operating differently, though, and there is reason to be concerned that lost time and clinical trial protocol deviations will slow the time-to-approval timeframe.[6]

What remains unchanged

The challenges wrought by C19 have simply exacerbated the challenges that CEOs already faced:

- How to incorporate technology - artificial intelligence (AI) in particular - to manage new, larger data sets and to target and communicate effectively with physicians, patients, advocacy groups, and key opinion leaders?
- How to manage risk when the dynamics of licensing and M&A activities related to portfolio management are changing dramatically?
- How to integrate alternate/digital marketing and sales channels?
- How to adopt to the acceleration of value-based health care, particularly as that affects both formulary placement and reimbursement?

What follows examines what CEOs have learned from their experiences to date and looks at how they have responded to different challenges.

How biotech CEOs are responding to the challenges posed by C19

Broadly speaking, many biotech CEOs are viewing the pandemic as a chance to turn lemons into lemonade. It is forcing them to address issues that they knew they would eventually have needed to address. There will likely be delays in the delivery of therapies currently in development, but the best ways to overcome the short-term challenges may also be the best ways to overcome the long-term challenges. Both short-term and long-term challenges require greater alignment between the clinical and commercial sides of the organization, a broader embrace of technologies such as big data and AI, and a new mindset when it comes to long-term business goals and the paths by which those goals are reached.

Transforming delay into opportunity

Shift happens; embrace the shift. This appears to be the attitude of some CEOs. Delays in development and the completion of clinical trials have provided an opportunity for some CEOs to reevaluate the goals that have driven many previous decisions. The message they are putting out is novel for some internal teams: Regulatory approval is not the finish line. Regulatory approval is a crucial milestone, but it is only one milestone on a longer corporate journey. Not even blockbusters become blockbusters without strong marketing and commercialization activities, and these activities cannot be relegated to post-approval.

CEOs are taking this opportunity to encourage their medical affairs teams to act as a bridge between clinical and commercial teams – not only to encourage the clinical and commercial team members to talk to one another but also to become invested in supporting one another. When managed well, the clinical side embraces the need to understand and work with the long-term marketing and commercialization goals in mind while also understanding that this awareness should in no way compromise their development efforts or the company's goal in meeting the needs of patients. Indeed, this understanding will help clinical operations personnel understand why there may be requests for insight and data that may not otherwise be self-evident. In parallel, marketing and commercialization teams gain a greater understanding of the importance of certain clinical and development decisions and processes, ensuring that they can operate in ways that support the company's mission of both serving patients and achieving market success.

CEOs are also acutely aware of the impact of any delays the organization is experiencing today. The simple fact is that a three- to six-month delay that a pharmaceutical company encounters today is not what will have the greatest impact on the business or the value of the asset in development. It's the three to six months that the company will lose at the end of peak-year sales or patent expiry, and that impact could be measured in the hundreds of millions of dollars. This makes a compelling argument for taking the time today to accelerate the institutional changes that will result in improved operational efficiencies because those operational efficiencies will be crucial when the company needs to do more and more with less and less time remaining before the product goes off patent.

Embracing technology

In many ways, the response to the C19 pandemic has served as a catalyst for health networks and patients to successfully advance through the adoption of telehealth and remote health care interactions. Building on this ever-growing foundation provides a real opportunity for biopharma across business lines for efficiency, accuracy, and savings if done correctly. Increasingly, organizations are moving away from viewing telehealth programs as temporary ways to comply with pandemic guidelines and embracing telehealth as a means to control costs, increase efficiency, and maintain quality.

AI, in all its incarnations, is also becoming more widely embraced. Biopharmaceutical executives are much more aware and confident of the impact of AI than before the pharma world became more virtual. In the November 2019 BCI poll of pharmaceutical executives, only 11% were confident that AI would make an impact in the next 12 months. However, that number had more than doubled to 25% by April 2020.[1] To be clear, the term AI is still a broad term that encompasses everything from machine learning to advanced

biocomputing programs that deliver enhanced diagnostic and treatment recommendations in real time. However, it appears safe to say we are at the beginning of a journey that holds great promise. The key challenge for biopharma organizations is to understand how, where, and when AI can add value both within an organization and within its operational processes. From those assessments will follow the necessary refinement of internal capabilities and adoption readiness.

Using technology to redefine clinical development

Looking at technology more broadly, the expectation among CEOs that digital health technology in general will impact the biopharmaceutical industry has soared since the onset of the pandemic. In November 2019, only 11% of biopharma leaders expressed high confidence in the positive impact of technology, but that number had more than tripled to 36% by April 2020.[1] Assuming this trend holds once social distancing requirements relax and tools such as telehealth are not expressly required, there are open questions about the role digital technologies will play in clinical trial and market launch plans.

Consider that the deployment of advanced technologies has created many high-quality (albeit incomplete) data sources that can be accessed to complement – or even substitute for – traditionally captured prospective data sets (both pre- and post-approval). While these databases may fall short in terms of data quality and consistency, and they may preclude opportunities to interact with or engage study investigators, real-world physicians, and patients, they present a relatively inexpensive path to data sets that may provide real value.

As previously noted, CEOs are increasingly using this time to encourage clinical and commercial teams to embrace both the organization's scientific and business goals. A new appreciation for these joined goals will have an impact on technology decisions at an early point in the overall planning cycle. Decisions that might inform trial design and monitoring will also have to take into consideration launch planning and the integrated design of market access materials and education programs. The early discussions will also need to consider remote monitoring and physician-patient virtual experiences and how they can be deployed and leveraged more easily and effectively.

This gives rise to other questions: Can patient monitoring specific to an indication/therapy be undertaken safely and effectively using remote digital technology rather than frequent in-clinic visits? Can an electronic alert or emergency response mechanism be developed to respond to a patient's needs, reduce risks, and measure compliance? Can these "remote health" features be built into the regulatory package so that physicians, patients, and payers all understand the benefits and requirements of this new paradigm? It is worth noting that new technology implementation timelines tend to be impacted by regulatory and privacy guidelines (e.g., HIPAA) and patient acceptance. The pandemic has provided a more favorable environment for digital health care to move forward at a faster pace than envisioned only a few months ago, but some vigilance in these areas will be required in the coming years to ensure ethical use.

Recognizing the importance of documenting the current standard of care (burden of disease) as a baseline against which to demonstrate the impact of their product in development (as well as post-launch), many companies are looking to better understand the impact of digital medicine on real-world clinical outcomes (as well as resource utilization and patient-reported outcomes). As above, gathering these insights efficiently and effectively requires greater alignment between clinical and commercial, for only then can the clinical operations teams see the value in documenting and striving for product approval within the new normal context.

Planning for market success from the start

As noted, the transformational challenges that CEOs had been confronting before the outbreak of the pandemic have not vanished. They remain urgent, perhaps even more so as a consequence of the pressure created by the pandemic. CEOs have been striving to get clinical, medical affairs, and commercialization teams to work together more effectively and efficiently. They are intent on breaking down the silos that preclude a closer working relationship with partners and removing the internal silos that keep these internal teams from working in a more cohesive and integrated manner. If they all understand the broader context in which their efforts take place, they can operate more effectively, efficiently, and expeditiously.

When CEOs succeed in bringing teams together, though, many things change. For example, teams can begin to prepare for post-approval commercial success of a new therapeutic during the clinical development process. This introduces discussions that are not typically held during the clinical development phase – about market launch planning, data, marketing and educational information requirements, and more – which can influence clinical development and study design. While this may seem only to shift the burden of such discussions forward by months or years, it can have the downstream effect of accelerating both regulatory and market stakeholder acceptance.

Moreover, the more technology plays a role in the development and delivery of a new therapy, the more questions need to be asked about the economic assumptions built into historical launch models. Economic analyses of the impact of a new therapy have been part of the launch planning process for a long time, but new ideas are needed about how to assess and predict the economic impact of a technology-enabled therapy in light of historical norms. How does digital health impact patient throughput efficiency, safety, and compliance? What is its impact on cost to the practice, facility, and payer? Answers to such questions may have a dramatic impact on launch planning.

Building new integrated channels

Technology is not the only factor influencing launch planning at an early date. Alternate sales and marketing channels were displacing older pharma sales models even prior to the pandemic. The BCI survey conducted late in 2019 indicated that 19% of executives expressed high confidence that new models would be effectively integrated.[1] It appears, however, that the pressure to develop those new sales and marketing channels has only increased as a result of the pandemic. As of April 2020, when more and more health care practices had begun to limit or even eliminate direct sales rep access to physicians, that same confidence level about the incorporation of new marketing and sales models among biopharma executives had climbed to 23%.[1]

Traditional field sales will not go away fully, but field efforts must be closely integrated with other sales channels (inside sales and MSLs in particular). MSLs may need to set the path forward, with inside sales and field sales supporting. This integration must be fostered early on so that, upon regulatory approval of a therapy, coordinated marketing and sales activities can commence to ensure that those few face-to-face interactions that do take place result in the greatest value. MSLs must begin engaging with early adopters during Phase II rather than Phase III, while working on the transition from a drug for a particular patient to drug portfolios to manage a patient population. Finally, pharmaceutical firms should develop a publication strategy designed to deliver peer-reviewed papers that support and reinforce the efforts of the customer-facing channels.

Expanding trial site horizons

The movement from traditional trial sites to sites staffed by active practitioners (rather than researchers) can become a positive shift for a pharmaceutical company. Active practitioner sites may be more likely to generate valuable real-world data. CEOs of smaller companies with limited funding may find this data particularly valuable if they see an exit involving a partnership or even the sale of their asset. CEOs should consider the commercially important factors and end points that may be obtainable simultaneously in a potentially pivotal clinical trial.

In response to the difficulties posed by the pandemic when it comes to "traditional" clinical trials, there is an increased interest in expanding trial options to include virtual, siteless, and even home-based trials. These study modalities introduce their own challenges in areas as diverse as data collection, reporter training, care provider certification, and more. They provide options for organizations intent on continuing trials already underway, as well as options that can be incorporated into new studies to reduce costs, gain new and wider insights, and deliver greater patient satisfaction.

Accommodating the changes wrought by value-based health care

The migration from a fee-for-service to a value-based health care (VBH) payment model has been underway for some time. In the late 2019 BCI survey, 15% of biopharma executives expressed a high confidence that VBH would have a significant impact on the industry over the next 12 months. However, when the pandemic arrived, that number climbed to 26%.[1]

That confidence stems in part because of a weakness in the fee-for-service system that the pandemic exposed: Fewer non-COVID patients are availing themselves of health care services that they would have sought in the absence of C19. That reality has resulted in lower revenues for hospitals and health care providers, even though the health care system itself is near capacity in some areas due to localized spikes in the pandemic.

Other changes to the traditional economics of health care are reflected in actions taken by Washington to reduce drug costs under a "most-favored-nation" mandate. These actions may result in profound changes to long-held assumptions and expectations and require pharmaceutical companies to develop whole new financial models to determine how and when clinical development and commercialization costs can be recouped. The strategic value of market order of entry may change entirely as regulatory sentiments evolve. In markets that rely heavily on health economic data and quality-adjusted life-year analyses, the first company to file for approval with a novel therapeutic may encounter far longer timelines to launch than the second or third company because the data that might support the first company's claims may only come into being as a result of the work completed by that first-to-market company. Subsequent arrivals on the field may be able to build on that data and reduce cost of development and time to market.

Given an existing clinical development/market launch process, how can biopharma respond successfully to a shift to VBH? CEOs that are having success suggest the following:

- Consider how to gain long-term differentiation through patient segmentation identified during clinical development.
- Consider how new diagnostic technologies can support patient segmentation. When are these technologies employed in clinical trial design to maximize effectiveness for launch? Precision medicine is moving far beyond specific cancer therapies.
- Consider how to develop real-world-evidence during clinical development that takes into account the cost and value of bundled services (such as diagnostics, bioinformatics, and other requisite components).
- Consider how to invest in health economics and outcomes research (HEOR) for optimal insights during a clinical development timeline.
- Consider how best to best capture supporting data about improved outcomes that new pricing paradigms and innovative service bundles will require in advance of market launch preparation activities.

As with so much else, the path to transformation, one that in this case helps the firm thrive amidst a transition to VBH, depends on the integrated efforts of both the clinical and business teams. The more effectively a CEO can foster a closer, more integrated working relationship between these sides of the enterprise, the more effectively and the more quickly these challenges can be addressed.

Redefining normal in a post-COVID era

Sooner or later, we will work in a world that does not require social distancing and constant mask-wearing, but that may have little impact on drug development and commercialization. Today's CEOs are finding efficient and effective work-arounds for the issues that have slowed drug development, and as long as those work-arounds result in greater efficiencies and more optimized outcomes, there may be few compelling reasons to return to a pre-COVID business as usual. Many of the processes and practices evolving in response to C19 will likely become the "new normal," even after the world gets the pandemic under control.

That said, best practices for operating in this "new normal" are emerging. Companies looking to get the most out of all steps in the clinical and commercial development continuum should keep these in mind:

1 | Establish and maintain early access to patient populations (particularly rare ones) to accomplish the following:

- Help optimize clinical trial protocols so as to be as patient-centric as possible.
- Improve the efficiency of patient (and site) recruitment.
- Get a jump start on post-approval patient engagement.

CEOs must also strive to ensure that their company's outreach to patient groups is truly as authentic as possible.

2 | Companies are encouraged to explore the viability of virtual (site-less) or direct-to-patient clinical trials that take advantage of digital data acquisition technologies and advanced study methods.

- Such technologies can dramatically reduce the cost of a study, though such technologies cannot be used in all studies.
- Such technologies can improve the participant's experience by reducing the burden of intrusive travel and site visits, a value that regulatory authorities have acknowledged.
- Key to the success of trials relying on such technologies is an unflagging focus on data quality and study efficiency, which can be managed in partnership with a CRO.

3 | Companies must augment the traditional launch planning process with new ideas to predict and maximize the positive economic impact of technology-enabled use measured against historical norms.

Many smaller biopharma companies will want to rely on third-party partners to help them work through these and related issues – including their RWE/RWD, data access, medical affairs, market access, market launch, and HEOR issues. CEOs may want to manage these issues in-house, but until the outlook for regulatory approval and commercial success is more certain, it may be more prudent – in terms of expertise, flexibility, and cost – to bring CROs and management consultant partners onboard. They are already set up to support those needs, and relying on their expertise during these uncertain times may simply make more sense from a strategic management standpoint.

Summary

COVID-19 has disrupted life for all but the most isolated individual on the planet. It has disrupted the manner in which biopharma companies develop, test, and commercialize products; it has disrupted attempts by pharmaceutical CEOs to transform their organizations into nimbler innovators whose clinical and commercial sides understand one another more fully and work together in a more streamlined and efficient manner. At the same time, C19 has trained a bright light on the reasons that CEOs have been striving to transform their organizations: The times that demand agility and flexibility, the times that require greater internal alignment and time- and cost-efficiencies, and the times that mandate the creative use of advanced technology are not in the future. These times are now.

Transforming a pharmaceutical company to respond more effectively and efficiently – both to the challenges created by C19 and those created by independent market forces – is the order of the day. CEOs must accelerate the evolution that needs to take place, because the time lost today can only be made up by greater efficiencies on the back end of a product's protected life, while simultaneously staying focused on the needs and expectations of employees, patients, regulators, and stakeholders. Everyone involved in bringing a novel therapy to market must work as a single team, with a full appreciation of their respective roles and responsibilities. Regulatory approval is neither the end nor the beginning of the race; it is merely the point where the baton is formally passed from one strong teammate to another (who has gotten a running start). It is the role of the CEO to ensure that the team has the cohesion, the tools, and the creativity to push the race to its true conclusion.

About Kineticos Life Sciences

Kineticos is an award-winning organization supporting Biopharmaceutical and Precision Medicine firms. Launched in 2007, Kineticos initially concentrated on strategy, licensing, and market access support for Precision Medicine firms. In 2012, Kineticos launched its Biopharmaceutical practice. In 2016, Kineticos launched its internal think tank, The Kineticos Research Institute, which includes the Biotech CEO Confidence Index, The Disruptor26 podcast series, white papers, How To's, and other relevant content. In 2019, Kineticos was selected as Triangle Business Journal's Life Science Consultant of the Year.

In 2020, with the launch of the Kineticos Disruptor Fund, Kineticos recognized the need for a new model to support life science start-ups integrating intelligent funding, biotech expertise, and thoughtful execution. Kineticos has a deep and talented community of advisors to support biotech formation and funding. Ongoing relationships with larger pharmaceutical and biotech companies provide our portfolio companies with numerous opportunities for research collaborations and non-dilutive funding.

Through its two practice areas—Biopharmaceutical and Precision Medicine & Diagnostics—the firm has experience working with companies across the life science industry ecosystem.

About Worldwide Clinical Trials

Founded by physicians committed to advancing medical science, Worldwide is out to change how the world experiences CROs – in the best possible way. From early phase and bioanalytical sciences through late phase, post-approval and real-world evidence, we provide world-class, full-service drug development services across a range of therapeutic areas, including central nervous system, cardiovascular, metabolic, general medicine, oncology and rare diseases. We never compromise on science or safety. We're never satisfied with the status quo. We're the Cure for the Common CRO. http://www.worldwide.com.

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