COVID-19 and the new pragmatism

The COVID-19 pandemic has taught us many lessons. One is that after the crisis passes, or is contained, the world will look and work very differently. The pharmaceutical industry is no exception.

While nothing is assured, one can presume with some confidence that there will be more generous incentives for companies to invest in developing vaccines and infectious disease drugs. The public and policymakers most likely will continue to push for the accelerated development of new and affordable medicines. This accelerated development will demand more real-world evidence (RWE) to establish efficacy and safety, and, given future concerns about travel, clinical trials will become increasingly decentralized and patient-centric to increase convenience for enrollees.

There is a theme emerging in all these changes: a new pragmatism.

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Clinical trials

Due to limited access to clinical sites, some trials have been put on hold. But for many others, sponsors and managers are transitioning to decentralized or virtual trials with remote monitoring and source document verification (SDV) to ensure that trials can continue, and participating patients can continue to benefit. As a pioneer in approaches to decentralized trials, Parexel has implemented technologies and new patient-focused innovations - such as eConsent, wearables, telehealth, telemedicine, and remote SDV – to continue facilitating Phase II and III studies.

Before the pandemic, many insurers, including Medicare, did not reimburse for telemedicine. Now they do, and they will likely continue to do so, spurring both increasing innovation in technology and higher rates of adoption.

Investment

Infectious disease programs currently represent less than two percent of the pharma development pipeline. The COVID-19 pandemic has revealed the dangers (and costs) of not having vaccines to hand, and society may be ready to invest more in drugs and vaccines to avoid future human and economic catastrophes.

To encourage greater investment in infectious disease, policymakers will need to address both "push" and "pull" incentives. While funding grants ("push") and regulatory incentives can help companies de-risk the early stages of development, they do not address the current risks to manufacturers by the adoption of generics and antibiotic stewardship by healthcare providers, resulting in infrequent brand prescribing and poor usage. "Pull" incentives could include market-entry rewards, such as payments over multiple years to companies after approval, or transferable vouchers that would extend the exclusivity period on other drugs in a company's portfolio.

Meeting the rise in demand for new and effective treatments may require new networks. For example, large pharmaceutical companies may work closely with small biotechs, charitable foundations, universities, and CROs to develop new products.

Regulations

In the last two months, 50 of the world's regulatory agencies have demonstrated a new flexibility by issuing new guidance on how sponsors should manage clinical trials. However, standards on GCP compliance have not been lowered, and sponsors need to maintain GMP and GCP compliance to protect their development plans, ensure ultimate regulatory approval, and preserve the lifecycle of their products on the market.

At the same time, manufacturing plants in receipt of regulatory enforcement letters are trying to remediate their operations, calling on experts for help. But those experts cannot travel to sites, and may not be able to do so for the foreseeable future. International guidelines allow for remote auditing, and experts are beginning to direct and monitor remediation efforts using video, virtual reality, and other advanced tools.

Once sponsors and CROs master this new regulatory environment – which has the potential to create new efficiencies, shorten response times, and reduce costs – there will be little scientific, operational, or financial incentive to return to old ways of operating.

Indeed, COVID-19 is raising questions about the impact of traditionally conservative regulatory thinking on drug development. Regulators, exercising greater pragmatism, are showing new interest in RWE and post-marketing surveillance. RWE also presents an opportunity to identify treatments for further study earlier, accelerate drug development, and leverage synthetic control arms. In other words, regulators appear to be moving from being risk-averse about RWE to prudently enthusiastic.

An opportunity in a time of crisis

We in the industry must ask ourselves if we have been creative in responding to COVID-19. Have we embraced new technologies? How have we changed the ways we do business, develop drugs, and treat patients – not only for COVID-19, but for every condition? If nothing else, the COVID-19 pandemic has shown us that the entire healthcare ecosystem must become more pragmatic to become more efficient and useful to patients. Our healthcare paradigm must shift to be better prepared to withstand the next global outbreak, and whatever comes after that. We have a duty to patients to learn from this experience and continue to innovate and, ultimately, deliver better healthcare in a changing world.

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With Heart

We're always available for a conversation

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