



Fast-forward: Will the speed of COVID-19 vaccine development reset industry norms?

May 13, 2021 | Article

A review of the funding, operational, technological, and regulatory factors that allowed for fast development of COVID-19 vaccines shows which will remain relevant for future efforts—and which won't.

DOWNLOADS

[↓ Article \(7 pages\)](#)

The standard view in the pharmaceuticals industry has been that it takes many years to develop a new drug. And, until recently, that has generally been true.

A McKinsey analysis of all new drugs developed since 2000 shows that the mean development timeline—from the start of clinical testing (Phase 1) to approval—is nearly ten years.^[1] The same holds true for new anti-infective vaccines: the development of vaccines for the human papillomavirus, shingles, and pneumococcal infections, for instance, clocked in at between nine and 13 years.^[2] Most academics and

pharmaceutical-industry stalwarts would consider a development timeline of less than five years to be highly unusual.

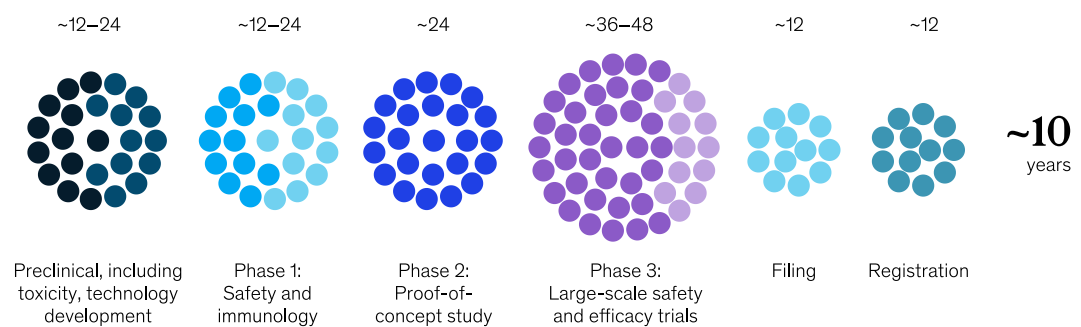
It is truly remarkable, then, that three COVID-19 vaccines were granted emergency-use authorization (EUA) or other forms of approval in Europe, the United Kingdom, or the United States by the end of 2020—just 11 months after the SARS-CoV-2 sequence was published and just eight or nine months after the first human doses were administered (Exhibit 1). Previously, the fastest vaccine development was that for the mumps virus, which took four years (from virus sampling to approval) during the 1960s.^[3]

Exhibit 1

Development times for COVID-19 vaccines were highly compressed compared with standard practice.

Vaccine development then and now, months

Sample baseline scenario,¹ (after multiple years of research)



Sample accelerated timeline,² (based on previous SARS/MERS research)

Development was simultaneous rather than sequential. Clinical phases were continued after subsequent steps were initiated.



¹Timelines can vary widely based on disease and trial designs.

²Patient safety was paramount despite the condensed timeline.

³Continuation of clinical development after emergency-use authorization.

**McKinsey
& Company**

At the time of this writing, 15 vaccine candidates have received emergency-use or full authorization in one or more countries, and more are expected in 2021. It is no exaggeration to say that the development and deployment of COVID-19 vaccinations is capturing and catalyzing the hopes of millions or even billions of people around the world. It is a scientific, industrial, regulatory, and logistical achievement that will make history.

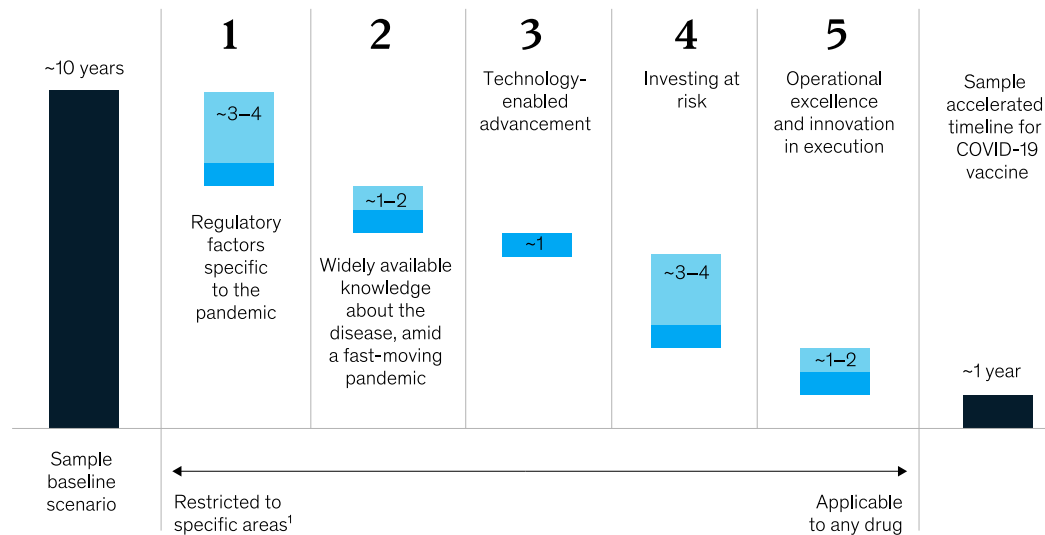
How was it possible? Several factors that are clearly related to the nature of the global humanitarian crisis made it possible to break molds and challenge orthodoxies in a state of *force majeure*. Companies and governments accepted a level of investment risk (billions of dollars) that was justified only because of the extreme nature of the crisis, and unprecedented levels of public funding were made available very quickly. Similarly, authorities and regulators were open to proceeding with drug development, even with risks, and made themselves available for conversations with sponsors on short notice.

From our own research, based on publicly available sources and conversations with industry experts and leaders at institutions that worked on COVID-19 vaccines, we have identified five areas where vaccine-development programs differed significantly from the norm: regulatory factors specific to the pandemic; widely available knowledge about the disease amid a fast-moving pandemic; technology-enabled advancements; investing at risk; and operational excellence and innovation in execution of drug development (Exhibit 2).

Exhibit 2

Five factors affected the speed with which COVID-19 vaccines were developed.

Potential time savings associated with five key development factors, years



Note: Time savings across acceleration categories are not cumulative and depend on critical development path.

¹For instance, other pandemic situations or areas of high unmet medical need.

**McKinsey
& Company**

The urgent drug-development measures taken in each of these areas are unlikely to be replicated in a noncrisis situation. But actions taken during the COVID-19 crisis have revealed some general lessons for pharmaceutical companies and others seeking to bring drugs and treatments to market faster.

Regulatory factors specific to the pandemic

The acute state of the COVID-19 pandemic in 2020 prompted an unprecedented level of acceleration of regulatory processes and interactions. For instance, regulatory applications for the first human doses of COVID-19-vaccine candidates were processed in less than a

week, instead of the typical 30 days. Clinical-development phases were started before prior phases had fully concluded: Phase 2 clinical development was started based on an interim readout from Phase 1 clinical testing. EUA was granted based on a rolling review from authorities, and data packages were amended as new information became available. In all cases, detailed follow-up was requested to ensure appropriate risk management—for instance, clinical trials must continue to collect long-term safety data.^[4]

While many of these measures are reasonable in a major humanitarian crisis, most seem unlikely to become status quo for all drug-development programs. But it is worth considering if some of these practices—for example, rolling regulatory review—may become more relevant for other diseases with high unmet medical need, such as rare diseases with high mortality rates or pathogens with antimicrobial resistance.

Widely available disease knowledge and a fast-moving pandemic

Critical information on COVID-19 was quickly made available to the entire scientific community. The coronavirus genome sequence was published on January 11, 2020,^[5] only weeks after the first pneumonia cases were discovered in China and several weeks before the World Health Organization (WHO) declared a global pandemic, on March 11, 2020. Many years of research and experience in related infectious diseases such as SARS and MERS were brought to bear in the design of the COVID-19 vaccines. For instance, reverse- and structural-vaccinology approaches that leveraged previous MERS-CoV studies enabled antigen design within 24 hours after the SARS-CoV-2

sequence was published.^[6] Although the clinical features of COVID-19 infections are subtle and varied, the comparatively straightforward testing for the presence of the virus ensured that barriers to speed could be broken down quickly.

The rapid spread of infection was a humanitarian tragedy, but it did speed up the development of vaccines, as trials were conducted in geographies with very high virus attack rates. The societal impact of the disease created enough urgency that healthy volunteers were recruited quickly for clinical studies. The cases of COVID-19 accrued at a much faster rate than vaccine developers had expected. The interim readouts for some of the earliest vaccine trials were planned at about 30 or 40 cases, but by the time developers agreed with the regulatory agencies and actually locked the database, they had upward of 90 cases—meaning readouts were available earlier (with much more data) than expected. Of course, these aspects are specific to the COVID-19 situation and may not apply to drug development more broadly.

Technology-enabled advancements

Among the remarkable features of the development effort for COVID-19 vaccines is the fact that the first two vaccines approved in Europe and the United States both use a novel platform technology (mRNA) that has never been used to develop an approved medicine. mRNA has been a hot topic in the pharmaceutical industry for several years, but it is an unexpected plot twist that this new technology would be the development platform for vaccines from Moderna and Pfizer–BioNTech; another mRNA-based vaccine is currently in late-stage development by CureVac.

The other novel platform technology being used is viral vectors, which had previously been approved for use in the development of Ebola vaccines but not for any other disease since.^[7] Several companies across the globe (among them, CanSino Biologics, Johnson & Johnson, Oxford–AstraZeneca, and Sputnik V from the Gamaleya Research Institute) have developed COVID-19 vaccines with viral-vector technology on timelines that were roughly equivalent to the mRNA-based products.^[8]

The mRNA and viral-vector platforms have both seen years of significant investment, so by the time the pandemic hit, they were ready for use. The platforms allow for fast development of vaccine candidates, adaptations as infections and viruses evolve, and quick scale-up of manufacturing. In the case of the mRNA program run by Moderna and the National Institute of Allergy and Infectious Diseases (NIAID), for instance, the first batch of clinical-grade vaccine material had already been produced on February 7, 2020—just four weeks after the genome sequence was published. The first patient was dosed on March 16, 2020.^[9]

The pandemic, and the associated government funding for vaccine development, prompted companies developing mRNA and viral-vector technologies to accelerate the validation and scale-up of their platforms. Notably, the vaccines that were being developed using established technologies, such as protein-based platforms or inactivated or attenuated viruses, moved almost as quickly as the programs using mRNA and viral-vector platforms. In all cases, companies had these technologies up and running (at different stages of maturity) and were able to mobilize them for COVID-19-vaccine projects.

Investing at risk

Developers of COVID-19 vaccines were able to move quickly in part because process steps that normally would have had to happen sequentially were carried out in parallel with other steps. Clinical-grade drug material was prepared before preclinical tests were completed. Companies made significant investment decisions (billions of dollars cumulatively across the companies involved) in manufacturing capacity, including conversion of existing labs and factories, based on limited information and at a much lower level of certainty than they would normally require. Companies wanted to do what they could to accelerate timelines in case trials proved successful, and they recognized that government and institutional funding was available for promising candidates.

All of this amounts to a high level of financial risk taking. The mindset for all parties was to get a working vaccine to market as quickly as possible. When a company is developing a drug for a market in which there are other treatment options, it will normally invest in making sure that the product is competitive compared with the standard of care—on efficacy and safety, of course, but also on physical characteristics, ease of use, and supply-chain considerations, which adds to drug-development timelines in most cases. In the case of a global emergency, when there is *nothing else* available on the market, the considerations are different.

Operational excellence and innovation in execution

Some companies involved in the development of a COVID-19 vaccine shifted to 24/7 lab operations early in 2020. The extreme nature of the situation and the sense of mission prompted individuals to adopt schedules that likely could not be sustained over the long term but were required in the moment.

At one company, the CEO scheduled daily meetings with the project team to speed up decision making—a far cry from the usual drug-development process, whereby information moves through multiple internal reviews by various committees before any decisions are made. Through the COVID-19 crisis, some developers have discovered the limitations in their traditional ways of working—processes that may be inefficient, even obsolete. A cleansheet approach to thinking about drug-development processes and decision making may be helpful, especially for top-priority programs in developers' portfolios.

Innovation in clinical-trial operations has also supported fast development of COVID-19 vaccines. For example, developers identified emerging hot spots using epidemiological models and used that information to open clinical sites in those locations. Most developers relied on a control-tower strategy to scrupulously track the progress of clinical trials at every stage: they monitored when patient samples were drawn, when they left the premises of the clinical trial, when they arrived at the lab, and so on.

Above all, the development programs for COVID-19 vaccines will be remembered for an unprecedented level of collaboration among mature, global pharmaceutical companies; young biotech companies; health authorities and regulatory agencies; and a range of public and private institutions that committed funding, research, and other resources.

Thousands of physicians at hospitals and clinics have executed the clinical trials; engineers at contract-manufacturing organizations, logistics companies, and government agencies have participated in global supply chains; and hundreds of thousands of frontline medical workers, digital-solutions developers, transportation workers, and government administrators at all levels have contributed. At the time of writing, roughly at the one-year mark of the start of the pandemic, more than 1.3 billion vaccine doses have been administered, albeit unevenly across countries.

Implications for the future of drug development

Many of the factors that helped compress development timelines for the COVID-19 vaccine were specific to this global pandemic and likely cannot be replicated in all future drug-development programs.

However, recent events may prompt governments and companies to reconsider how they value their pandemic preparedness and prioritize their investments accordingly—for instance, funding research on pathogens that are at risk of causing the next pandemic. Additionally, there are other, broader lessons for companies and governments on how to help accelerate the development of new medicines.

Operational excellence and innovation. There are three operations-based lessons companies can take from COVID-19-vaccine programs. The first is to rethink the design of their drug-development programs—for example, simplifying and applying innovative trial designs (by combining Phase 1 and Phase 2 trials) and measuring the primary aspects of a drug, rather than loading up trials with secondary endpoints and assessments. The second is to cleansheet internal

decision-making processes; companies that review their processes from the ground up have an opportunity to cut out the white spaces and obstacles and find the shortest-possible path to critical decisions. And the third is to revisit the execution levers currently used in clinical trials—for instance, deploying predictive modeling in order to select trial sites, enabling higher levels of automation of data management and writing, using agile ways of working to optimize submission timelines, and establishing a control tower to better track and plan studies.

Smarter application of investment at risk. Companies invested at risk to help develop COVID-19 vaccines, a concept that is not new in drug development but was certainly practiced to the extreme in this situation. Now that they have seen the levels of acceleration achieved, companies should feel emboldened to invest at risk in other priority programs that merit the attention—for instance, in transformative therapies that can address unmet medical needs, or in initiatives that could have an outsize impact on future corporate performance.

Regulatory collaboration. Regulators took extraordinary steps on a number of fronts during the public-health emergency, including increasing the frequency and intensity of sponsor engagement. While this level of engagement would likely be difficult to sustain and replicate for every product being developed by the industry, the concept of regulatory collaboration has been applied by many agencies to facilitate alternate pathways in drug and medical-device development over the past decade. Examples include the US Food and Drug Administration's breakthrough therapy designation, fast-track designation program, and the Real-Time Oncology Review pilot. Similarly, the European Medicines Agency created its accelerated-assessment timetable and guidelines, and Japan's Pharmaceuticals and Medical Devices Agency developed its Sakigake designation program. The expedited medical-product

development that has occurred during the COVID-19 pandemic may provide fresh inspiration for the next generation of such programs.

Leaders in the pharmaceutical and biotechnology industries are debating about which parts of this hyperaccelerated development cycle are ephemeral and which parts will live on. Most of the COVID-19-specific factors that sent ecosystem players into overdrive clearly will not be present in most traditional drug-development scenarios. Still, there are lessons companies can take from this experience to potentially reduce development timelines by several years, including revamping their design and execution of clinical trials, their approach to risk investment, and their engagement with regulatory agencies. The companies that can make changes in these areas can trigger lasting transformations—and bring life-changing therapies to patients that much faster.

1. Pharmaprojects; McKinsey analysis, October 2020.
2. EvaluatePharma; Clinicaltrials.gov; Pharmaprojects; press search.
3. The circumstances of developing a vaccine for the mumps virus were very different from those associated with developing a vaccine for COVID-19. The mumps virus had been present for decades, and a moderately effective vaccine candidate already existed by the end of World War II.
4. “Emergency Use Authorization for vaccines to prevent COVID-19: Guidance for industry,” Federal Drug Administration, February 22, 2021, [fda.gov](https://www.fda.gov).
5. Edward C. Holmes, “Novel 2019 coronavirus genome,” *Virological*, January 11, 2020, virological.org.
6. Kizzmekia S. Corbett et al., “SARS-CoV-2 mRNA vaccine design enabled by prototype pathogen preparedness,” *Nature*, August 5, 2020, [nature.com](https://www.nature.com).
7. I. V. Dolzhikova et al., “Viral-vectored Ebola vaccines,” *Acta Naturae*, 2017, Volume 9, Number 3, pp. 4–11, actanaturae.ru.
8. At the time of this writing, extremely rare but severe adverse events linked to the Oxford–AstraZeneca and Johnson & Johnson vaccines had emerged—vaccine-induced immune thrombotic thrombocytopenia—and were under investigation.

9. "Phase 3 clinical trial of investigational vaccine for COVID-19 begins," National Institute of Allergy and Infectious Diseases, July 27, 2020, [niaid.nih.gov](https://www.niaid.nih.gov).

ABOUT THE AUTHOR(S)

Gaurav Agrawal is a partner in McKinsey's New York office; **Robert Hermann** is a consultant in the Zurich office, where **Rosa Poetes** is a partner and **Michael Steinmann** is a senior partner; and **Martin Møller** is a senior partner in the Copenhagen office.

The authors wish to thank Jennifer Heller, Harriet Keane, Katarzyna Smietana, Michelle Suhendra, and Eli Weinberg for their contributions to this article.

This article was edited by Roberta Fusaro, an executive editor in the Waltham, Massachusetts office.

EXPLORE A CAREER WITH US

[Search Openings](#)