Innovation Accelerated: Factors Enabling Rapid COVID-19 Vaccine Development

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Innovation Accelerated: Factors Enabling Rapid COVID-19 Vaccine Development

Case Study

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Abstract

On March 11, 2020 when the World Health Organization declared the novel coronavirus (COVID-19) a global pandemic the world’s governments and industries rallied to combat the virus in various ways. From the private sector, several industries such as distilleries and automobile manufacturers were able to re-tool assembly lines and divert supply chains to create much needed Personal Protective Equipment, hand sanitizer, and ventilators. However, the task to create a novel vaccine, test therapies, and ultimately defeat the virus on a biological level can only be achieved through the pharmaceutical sector. The unique nature of the SARS-CoV-2 virus, which causes the COVID-19 disease, renders traditional quarantine and contact-trace measures less effective. Scientists agree, vaccines are the “most effective approach” and are “urgently needed” to be used as an “important tool” in defeating COVID-19 to enable society and economies to fully open back up. Fortunately, unlike past vaccine development, in less than 10 months several vaccines are already in phase 3 clinical trials and are on track to be approved in early 2021. This case study examines the environmental factors that allowed the pharmaceutical sector to levy a robust response to the pandemic by creating vaccines and advancing cutting edge science in record time.
The world’s top scientists, leading companies, research universities, and public health regulators are working at unprecedented speed to develop a vaccine in the shortest amount of time possible while maintaining exemplary safety and testing efficacy. While the world has faced similar pandemics before, the focus on a vaccine is due to unique factors that make the novel SARS-CoV-2 virus more transmissible, and reliable test-trace and quarantine measures less effective.

Most notably, when compared to SARS-CoV, MERS-CoV, and pandemic influenza, SARS-CoV-2 has the highest transmission rate in the 2.5 range. This is possible due to viral shedding that lasts for a prolonged period and begins in individuals when they are presymptomatic and even asymptomatic. In addition, high viral loads are detected in the first few days. These factors that contribute to high transmissibility “make isolation and quarantine of patients with SARS-CoV-2 and their contacts much more challenging and less effective, as it has to be done as soon as possible after illness onset in order to reduce transmission.”

Ultimately, it means defeating COVID-19 would require accelerated innovation and production of new diagnostics, therapeutics, and vaccines. As a response to the global effort needed, the World Health Organization initiated the Access to COVID-19 Tools (ACT) Accelerator in April 2020. It acknowledges that “innovative COVID-19 diagnostics, therapeutics and vaccines are needed – in record time and at record scale and access – to save millions of lives and countless trillions of dollars, and to return the world to a sense of normalcy.” It commits collaborators, including the International Federation of Pharmaceutical Manufacturers & Associations, GAVI the Vaccine Alliance, and the Bill and Melinda Gates Foundation, among others to “the shared aim of equitable global access to innovative tools for COVID-19 for all.”

To this end, industry associations such as PhRMA, Bio, and IFPMA have published commitments to screen and test all potential therapies in their vast libraries, expand manufacturing capacity, and to collaborate and coordinate with governments to ensure when treatments and vaccines are approved that they are available.

Despite the need and dedicated commitment, history suggests a vaccine could be decades away. Vaccines still don’t exist for many terrible diseases known for decades. For instance, there is still no vaccine for SARS-CoV, the closest cousin to SARS-CoV-2, even though it was discovered 18 years ago; it killed 770 people and infected 8,000 in two years. Other diseases that have plagued humanity such as dengue fever, discovered in 1907, Ebola, discovered in 1976, or rotavirus, discovered in 1973, only recently had vaccines

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8. IBID
9. IBID
11. IBID
12. PhRMA, “Our Commitment To Beat Coronavirus.”
13. IFPMA, “Global Biopharmaceutical Industry Pulling out All the Stops to Address Coronavirus Public Health Crisis – IFPMA.”
14. Snibbe, “Here’s a Realistic Timeline for a Coronavirus Vaccine – Orange County Register.”
approved to prevent infection in 2015,15 2019,16 and 200617 respectively. Studies estimate those diseases annually infected over 200 million people and killed 500,000,18 19 20 21 22 23 these numbers are rapidly diminishing as populations become inoculated. On average, it usually takes 10 years24 to develop a vaccine; the mumps vaccine moved the fastest from concept to approval in just four years. It should be mentioned that other diseases such as HIV, discovered in the 1980s, and malaria, known since the 1800s, continue to wreak havoc without a vaccine; they kill about a million people annually.25 26

Humanity’s struggle to contain diseases, though long and costly, are not in vain. Each has allowed science to advance rapidly and provided lessons to prepare humanity for the next novel outbreak. Perhaps the outbreak that offers the best public health guidance for responding to the COVID-19 pandemic is the novel 1918 Spanish flu pandemic. An influenza that originated in birds, it similarly spread quickly across the world with a slightly smaller transmission rate than SARS-CoV-2. The main difference in outcome between the two is that 95 percent of deaths from the 1918 flu occurred in those younger than 65, whereas only .6 to 2.8 percent of COVID-19 deaths occur in that population.27 A similar response from the global scientific community led to historic scientific advancements. For example, Thomas Francis, Jr., MD and Jonas Salk, MD developed the first inactivated influenza vaccine in 1955 and pioneered the use of fertilized chicken eggs to produce it, a technique still used to produce annual flu shots.28

Similarly, the COVID-19 vaccine pipeline contains a few firsts for science as well, not to mention being on track to reach regulatory approval for use less than 12 months from when the pandemic was declared.

17. CDC, “Rotavirus Vaccination | For Providers | CDC.”
22. CDC, “About Dengue.”
23. CDC, “Figure 3 - Global Illness and Deaths Caused by Rotavirus Disease in Children - Volume 9, Number 5—May 2003 - Emerging Infectious Diseases Journal - CDC.”
24. Steckelberg et al., “These Are the Top Coronavirus Vaccines to Watch.”
27. Petersen et al., “Comparing SARS-CoV-2 with SARS-CoV and Influenza Pandemics.”
Innovation at Warp Speed:

Since the start of the COVID-19 pandemic, researchers and medical personnel have pushed for quick developments of vaccines, treatments, and diagnostic tools to help combat rising COVID-19 cases. The discovery process leading to innovations and medical breakthroughs is only one part of the battle. All products eventually developed as vaccines, therapeutics, diagnostic tools, etc., need to be examined by government health regulators to ensure they are safe and effective. For example, in the U.S. the Food and Drug Administration (FDA) is responsible for granting final market approval while in the European Union it is the European Medicines Agency (EMA). Each may rely on coordination and assistance from other agencies. Other countries have their own regulatory agencies; some may utilize mutual recognition agreements with FDA or EMA.

In its response to COVID-19, the Trump administration formed Operation Warp Speed to coordinate efforts between several agencies including Biomedical Advanced Research and Development Agency, Health and Human Services, the Centers for Disease Control, and the National Institutes of Health to accelerate development, manufacturing, and distribution of vaccines. The Food and Drug Administration\(^{29}\) formed the Coronavirus Treatment Acceleration Program (CTAP) and Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Partnership to provide a myriad of assistance\(^{30}\) from guidance on forming clinical trials, issuing Emergency Use Authorizations, and subject matter expertise. Altogether these efforts on the regulatory side are coming together to approve, without sacrificing efficacy, novel vaccines with a supply of 300 million doses, with additional doses in stock in ten months. This is a dramatic improvement to the usual 10-15 years\(^{31}\) it typically takes a novel vaccine to be discovered and approved for the market.

Therapies and Vaccine Candidates in the Pipeline:

According to the latest analysis\(^{32}\) from the industry, there are 773 unique compounds in clinical trials to address COVID-19: 194 are vaccines, 213 are antivirals, and 366 are treatments. Only three months after the WHO declared the pandemic the FDA issued its first EUA for treating COVID-19; it was for Gilead’s remdesivir which had progressed from late-stage trials. Concerning vaccines, as of mid-November 2020, thirteen have entered into phase 3 clinical trials.\(^{33}\) The leading candidates are all novel vaccines created by companies in the private sector: Moderna, Johnson and Johnson, Pzifer, and AstraZeneca in partnership with Oxford University. Below we take a snapshot behind each leading vaccine effort to examine factors that enabled them to reach phase 3 clinical trials before others.

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29. FDA Research, "Coronavirus Treatment Acceleration Program (CTAP)."
30. FDA Commissioner, "Coronavirus Disease 2019 (COVID-19)."
32. Bio, "BIO COVID-19 Therapeutic Development Tracker | BIO."
33. Corum, Wee, and Zimmer, "Coronavirus Vaccine Tracker."
MODERNA

As a startup biotech, Moderna has been capturing headlines since its founding in 2010. Its founder, Stéphane Bancel, formed the company to pioneer breakthrough mRNA technology to deliver vaccines and drugs to the body’s cells. The mRNA disruptive innovation\(^\text{34}\) approach differs from common vaccines which rely on a watered down, inactivated, form of a virus to signal to the body what type of antigen to make. Instead mRNA delivers the exact code, not the virus, of the antigen researchers design for the most effective immune response. Besides eliciting a targeted immune system response, the mRNA process offers two additional benefits. First, the discovery process is much quicker as it mostly relies on computer assistance for designing the antigen. Secondly, relevant for addressing highly transmissible COVID-19, production of mRNA vaccines is quick and scalable as it doesn’t involve labs to grow, purify, and then inactivate the virus.

The science has been sought by several leading pharmaceutical firms since it was theorized decades ago, and indeed early on Bancel raised capital from AstraZeneca and Merck to partner on specific therapies and vaccines. What enabled Moderna to be positioned in the lead for mRNA research and development — without any approved mRNA vaccines or therapies under the company’s belt — was Bancel’s early focus on “filing broad and deep intellectual property”.\(^\text{35}\) This enabled the company to attract institutional funding, as well as know-how from leading researchers in the field.

Moderna developed its mRNA-1273 to fight COVID-19 in just 25 days\(^\text{36}\) after receiving the genetic sequence of SARS-CoV-2 from Chinese authorities. Early results from clinical trials, 283 days later, show it is 94.5%\(^\text{37}\) effective.

PFIZER AND BIONTECH

Pfizer, in partnership with German pharmaceutical company BioNTech, are leading in the fight against COVID-19 with another mRNA-based vaccine candidate: BNT162b2. The phase 3 clinical trial of the vaccine began on July 27 and in a recent report released by Pfizer, the vaccine candidate was found to be more than 90% effective.\(^\text{38}\) With this discovery and based on its production progress, Pfizer expects to deliver 50 million doses before the end of 2020 and finish filling the U.S. government’s order for 100 million doses in early 2021, producing in total 1.3 billion doses in that year.\(^\text{39}\)

\(^{34}\) Bahl et al., “Preclinical and Clinical Demonstration of Immunogenicity by MRNA Vaccines against H10N8 and H7N9 Influenza Viruses.”

\(^{35}\) Dickman, “Moderna Therapeutics.”

\(^{36}\) Moderna, “Moderna’s Work on a COVID-19 Vaccine Candidate | Moderna, Inc.”

\(^{37}\) Moderna, “Moderna’s COVID-19 Vaccine Candidate Meets Its Primary Efficacy Endpoint in the First Interim Analysis of the Phase 3 COVE Study | Moderna, Inc.”

\(^{38}\) Pfizer, “Pfizer and BioNTech Announce Vaccine Candidate Against COVID-19 Achieved Success in First Interim Analysis from Phase 3 Study | Pfizer.”

\(^{39}\) Ibid.
Pfizer has a 150-year history of achieving breakthrough innovations in health. It created the first smallpox vaccine, the first combined vaccine for preventing diphtheria, pertussis & tetanus, and manufactured millions of doses of the first trivalent oral poliovirus vaccine.\(^40\)

It’s COVID-19 vaccine partner, startup BioNTech, was founded in 2008 focused on developing customized medicines to enable a patient’s immune system to target specific cancer cells.\(^41\) In the search for breakthrough innovations to enable customized medicines, BioNTech also sought mRNA technology, and similarly has not seen one of its therapies or vaccines make it all the way through clinical trials to market either. However, they both licensed innovations from the early scientists that discovered a way to make the technology work: Katalin Karikó and Drew Weissman.\(^42\) Later, BioNTech hired Karikó to be senior vice president. They continue to compete in producing innovations that deliver the mRNA into cells.

**JOHNSON & JOHNSON**

Another company making headway with a vaccine candidate is Johnson & Johnson (J&J). In partnership with the Beth Israel Deaconess Medical Center, J&J has taken advantage of their years of experience with adenovirus serotype 26, or Ad26. Itself a mild virus very good at penetrating cells, J&J scientists had modified it already to deliver HIV proteins to prime the immune system to guard against HIV. That vaccine, Ad26.Mos4.HIV,\(^43\) is currently in stage 3 trials. J&J has other vaccines that use Ad26 for Zika and RSV in clinical trials. J&J has one vaccine, used to prevent Ebola, that uses the Ad26 viral vector strategy that has been approved by the EMA and effectively curbed outbreaks in the Congo.

To respond to COVID-19, J&J and its team at Janssen Pharmaceutical Companies have simply re-formulated Ad26 to deliver the coronavirus gene that directs production of its spike protein.\(^44\)

The technology to use the adenoviral vectors was originally developed in large part by Crucell which formed in 2000 as a pioneering startup using viral vectors as a delivery platform. By 2006 it became the sixth largest vaccine company in the world. Ultimately, it was acquired by J&J in 2010 along with its patents and know-how.

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40. Pfizer, “History of Vaccines | Pfizer | Pfizer.”
42. Garde, "The Story of mRNA.”
Through Operation Warp Speed, J&J received $456 million\textsuperscript{45} from the U.S. government to support the production of their vaccine in March. Beginning their clinical trials in July, J&J was able to successfully enter phase 3 clinical trials in September. However, in mid-October J&J put their phase 3 clinical trial on hold when a volunteer fell into unexpected illness. Out of an abundance of caution, J&J decided to pause their clinical trial, and after a week resumed. J&J anticipates they will have a fully functional vaccine available by early 2021.\textsuperscript{46}

In August 2020,\textsuperscript{47} J&J announced an agreement with the U.S. government to produce 100 million doses of its vaccine with support of $1 billion from the government to boost manufacturing capacity.

**ASTRAZENECA**

AstraZeneca in collaboration with the University of Oxford, and it’s company Vaccitech, has invented COVID-19 vaccine candidate AZD1222.\textsuperscript{48} It has already demonstrated a “robust immune response in all participants in early phase trials.”\textsuperscript{49} The vaccine, like J&J’s is based on using engineered adenoviral vectors. The technology has been in development for over thirty years, has a record of success fighting Ebola, and promising results in HIV and Zika trials. Only one adenoviral vector vaccine is used commercially,\textsuperscript{50} ONRAB, used to vaccinate wild animals from rabies.\textsuperscript{51}

The Trump Administration, through Operation Warp Speed (OWS), reached an agreement in May 2020 for AstraZeneca to make available 300 million doses of AZD1222,\textsuperscript{52} with first doses available in October 2020. AstraZeneca also has a second candidate AZD7442, a long-acting antibody (LAAB) combination, designed to prevent infection up to 12 months. The company received funding of $486 million for two phase 3\textsuperscript{53} clinical trials for AZD7442 and to supply 100,000 doses by the end of the year, and the option to acquire 1 million later. This is in addition to $25 million received from OWS for the discovery and evaluation of the monoclonal antibodies as well as phase 1 clinical trials to assess safety, tolerability, and pharmacokinetics.

\textsuperscript{45} Division, "HHS, DOD Collaborate With Johnson & Johnson to Produce Millions of COVID-19 Investigational Vaccine Doses."
\textsuperscript{46} Rattner, "Coronavirus Vaccine Frontrunner Pfizer Delivers Key Trial Data – Here’s Where the Other Vaccines Stand."
\textsuperscript{47} Kelly, "5 Latest Facts About Johnson & Johnson’s Investigational COVID-19 Vaccine."
\textsuperscript{48} Astrazeneca, "COVID-19 Vaccine AZD1222 Showed Robust Immune Responses in All Participants in Phase I/II Trial."
\textsuperscript{49} Kelly, "5 Latest Facts About Johnson & Johnson’s Investigational COVID-19 Vaccine."
\textsuperscript{50} "Adenoviral Vectors Are the New COVID-19 Vaccine Front-Runners. Can They Overcome Their Checkered Past?"
\textsuperscript{51} National Research Council of Canada, "Keeping Our Furry Friends Healthy: Artemis Technologies Inc. Partners with the NRC to Produce Successful Commercial Rabies Vaccine Bait."
\textsuperscript{52} HHS, "Trump Administration’s Operation Warp Speed Accelerates AstraZeneca COVID-19 Vaccine to Be Available Beginning in October."
\textsuperscript{53} HHS, "Trump Administration Expands Collaboration with AstraZeneca to Develop and Manufacture an Investigational Monoclonal Antibody to Prevent COVID-19."
STATE BACKED VACCINES

With the race to develop a tested COVID-19 vaccine being dominated by private biotech firms located in the U.S. and the UK, China and Russia have moved quickly to develop, produce, and distribute their own vaccines using state-owned enterprises. In addition, there is at least one private firm in China. They have loosened emergency use authorizations for them allowing hundreds of thousands to receive doses before clinical trials are finished and results are scrutinized by independent observers. In China, there are four leading vaccine candidates, two developed by Beijing-based research institute Sinopharm, a state-owned enterprise, in collaboration with the Chinese regulator; another by CanSino Biologics in partnership with the Chinese military; and one by Sinovac. However, there has been cause for concern around the world regarding China’s fast-track approval process for vaccine candidates. With China’s drug regulatory process being tied to the Beijing Ministry of Health, scientists around the globe say there needs to be more transparency over trial data and how trials meet safety and regulatory requirements before the vaccines gain widespread use.

Nonetheless, according the chairman of its China National Biotech Group, Sinopharm has given out approximately 350,000 doses of its vaccines outside clinical trials. In reaction, experts outside China, such as Dr. Arthur Caplan, head of medical ethics at the Grossman School of Medicine at New York University, have called the practice “reckless and dangerous.”

The vaccine shrouded behind even more opaque efficacy standards is Russia’s Sputnik V. Developed by Gamaleya National Research Institute of Epidemiology and Microbiology and funded by a sovereign wealth fund, regulators there skipped phase 2 trials and approved it before starting phase 3 trials. The small pool of just 20 cases of COVID-19 in the phase 3 trial used by Gamaleya to claim the adenoviral vector based vaccine was 92% effective, would not have been accepted by the FDA. That has not prevented Russia from signing preliminary deals with more than 10 countries to deliver 1.2 billion doses.

There is a concern that China and Russia could be using the vaccines as political leverage when entering in deals with individual countries to obtain future political or economic influence. Biotech companies located in the U.S. UK, and EU are signing commitments to deliver initial doses of vaccines to several governments, notifying the world in highly transparent and public press releases. On the other hand, Chinese and Russian state-owned biotech firms are creating agreements with middle and low-income nations, such as Brazil, Indonesia, Mexico, and Argentina, but keeping the terms of the arrangement confidential.

56. TrialSite, “Russia’s Sputnik V Expands to UAE.”
58. Kantchev, “Russia Strikes Deals to Sell Its Coronavirus Vaccine Internationally.”
59. Ibid.
60. Cyranoski
Pre-positioning for Pandemics

In accordance with the industry commitment to screen and test all potential therapies to treat COVID-19, many of the vaccines and therapies in clinical trials are being repurposed as they were developed and approved to treat similar viruses or COVID-19 symptoms, such as dexamethasone. While others, such as regeneron and remdesivir were pre-positioned, already in trials to treat similar viruses. The strategy to use therapies that have already been in trials is process-efficient as the potential candidates have been discovered and their safety, dosage, pharmacokinetic, pharmacodynamic profiles are already known. In short, it allows for phase 2 or phase 3 trials to begin earlier than novel therapies or vaccines.61

Drug repurposing and pre-positioning led to new approvals for therapeutics to be used to treat COVID-19. Two of the most notable therapies are remdesivir and regeneron. Remdesivir was invented by Gilead through decades of research and had been in clinical trials to treat Ebola, and in vitro laboratory tests and in vivo preclinical animal models to test against SARS and MERS, similar coronaviruses. Preclinical results were promising, but the number of potential study participants dwindled as the public health strategies succeeded to control and eliminate spread of the viruses. Fortunately, the past trials positioned Gilead to quickly generate preclinical trial data to begin phase trials of remdesivir as a potential treatment for COVID-19. In May, three months after Gilead initiated phase 3 trials, the FDA issued the first Emergency Use Authorization for COVID-19 treatment to the company62 after the NIH concluded patients receiving remdesivir in the trial recovered sooner and had a reduced mortality rate.63

Likewise, Regeneron developed REGN-EB3 to treat the deadly Ebola virus, as a new antibody cocktail. The company used the same VelociSuite technologies to create REGN- Cov2, a monoclonal antibodies cocktail to treat COVID-19. Preclinical and clinical trials were supported by an agreement with BARDA using the same technology to develop Regeneron’s therapeutic to treat Ebola.64 The company was the first to receive OWS support to develop a COVID-19 therapeutic: $450 million for 70,000 to 300,000 doses with the first batches available by the end of 2020.65 Regeneron’s Ebola treatment, Inmazeb, became the first FDA approved treatment for Ebola virus later in the year.66

61. Singh et al., "Drug Repurposing Approach to Fight COVID-19.”
62. FDA Commissioner, "Coronavirus (COVID-19) Update.”
63. NIH, "Early Results Show Benefit of Remdesivir for COVID-19.”
64. HHS, "HHS, DOD Collaborate with Regeneron on Large-Scale Manufacturing Demonstration Project of COVID-19 Investigational Therapeutic Treatment.”
65. Ibid.
66. FDA Commissioner, "FDA Approves First Treatment for Ebola Virus.”
The prevalence of private European and American companies advancing the more prominent COVID-19 therapies begs the question – are there institutional arrangements that allow them to be fertile grounds for innovation?

The International Property Rights Index finds an almost perfect correlation of .92 when comparing property rights overall with the Global Biotech Innovation Index. Robust intellectual property (IP) rights protections are associated with de-risking the type of long-term, capital-intensive investments needed to pioneer breakthrough innovations. Consider that it typically takes 12 years to go from discovery to market approval, costs on average $2.8 billion, and less than 10 percent actually make it all the way through. IP rights ensure firms will own the knowledge, know-how, and final product of their work along with a period of market exclusivity to recoup research & development costs and fund the development of the next generation of medicines in their pipeline.

Using data from Bio, COVID-19 Therapeutic Development Tracker and the International Property Rights Index, there is an observable relationship between where companies participating in COVID-19 therapy development choose to locate and property rights protections. Overall, the top 20% of countries with the strongest protections of property rights are the headquarters for companies responsible for 73% of COVID-19 therapies in development. Focusing on the IP component of the index, the 15 countries in the highest range [8.0 to 8.9] are the headquarters for the companies conducting 85% of COVID-19 therapies in development. On the high end, by far, the United States is the outlier, as it is the headquarters for companies responsible for 400 therapies in development, 5% of the world’s total, or 2,798% more than the average number of therapies from countries with an IP score of 8.0 or greater. The other outlier is China, the average number of therapies in development for countries with a score of 8.0 or greater on the IP sub-index is 13, discounting the United States. China with an IP score of 6.02 is the headquarters for companies responsible for 38 therapies in development, more than any OECD country besides the United States. Of the 82 countries on the Index with a lower score in the IP component, only 4 are the headquarters for companies participating in COVID-19 therapeutic development: India, Turkey, Russia, and Thailand. It should be noted, it is state-owned enterprises in Russia and China leading COVID-19 therapy development. Overall, 74% of unique compounds in development to address COVID-19 come from small enterprises.

In order to accelerate innovation and cultivate a positive-sum competitive environment where the type of biotech startups like those pioneering COVID-19 vaccines and therapies can thrive, it is incumbent on governments to provide robust intellectual property rights protections.

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67. Carciente, "International Property Rights Index 2019."
Barriers to Access COVID-19 Vaccines

In the early days of the pandemic models predicted losses up to 1.1 million in the U.S. under the best mitigation efforts, including social distancing and mask wearing, and 2.2 million losses without mitigation.68 Countries scrambled to prepare emergency supplies, and for many that included "sicken thy neighbor" export curbs and import taxes which raised the cost of trading much needed medical supplies across borders.69 In an effort to ensure vaccines and therapeutics would be available when approved, several governments including Canada, Brazil, India, South Africa, and others raised the idea of waving exclusivity granted by intellectual property rights for COVID-19-related pharmaceuticals and medical products.

The pandemic has caused tremendous and irreparable harm. As daily cases rise to all-time highs the U.S., the global total death count has reached 1.3 million.70

However, as the year closes with 12 vaccines in FDA phase 3 clinical trials – two of which report from initial data that they are more than 90% effective – the end is in sight.

At the same time the Coalition for Epidemic Preparedness Innovations; GAVI, the Vaccine Alliance, the World Health Organization and member countries have made strides in funding COVAX an initiative to facilitate vaccine development and manufacturing of 2 billion doses to end the acute phase of the pandemic in 2021. The COVAX portfolio includes nine COVID-19 vaccines71 receiving funding to produce hundreds of millions of doses.

As illustrated in this report, all late stage vaccines in development in the U.S. and most in the COVAX portfolio are the result of decades of discovery research, often by small startups, that laid the groundwork for companies, universities, and state-owned enterprises to be able to produce novel vaccines in record time. Private sector companies and universities where legislation permits research institutions to own and market intellectual property from government-funded research has led the way. They represent billions in long-term invested capital, cutting-edge science, intensive regulatory assistance, and the zenith of positive-sum collaboration and competition. While others have advanced rapidly to capture headlines, the clear decision to achieve progress through shortcuts rather than a scientific process casts a permanent shadow over their efficacy.

Instead, in the coming weeks as vaccines are approved, absolute barriers will become more apparent. A vaccine approved by the FDA or EMA is not automatically approved in other countries, and vice versa.

68. Reynolds, "How One Model Simulated 2.2 Million U.S. Deaths from COVID-19."
69. Evenett, "Sicken Thy Neighbour."
70. Johns Hopkins University Coronavirus Resource Center, "Tracking: Follow Global Cases and Trends."
71. CEPI, "Our Portfolio."
Countries have different quality control testing requirements sometimes requiring data and assays to be transported to government labs. Many have divergent clinical labelling requirements. Often clinical trial requirements can differ affecting design and approval timelines. Documentation review may require a sequential committee process, while other hurdles affect how clinical trials can be exported. These broad differences in regulations add time and costs to approving vaccines – after other regulators like the FDA or EMA already have. In addition, each vaccine requires a different logistics supply chain to ensure inputs can be delivered in abundance safely, and finished doses can be transported around the world efficiently at correct temperatures.

Fortunately, these two regulators have had a long-standing Mutual Recognition Agreement (MRA) that allows drug inspectors to rely upon information from drug inspections conducted within each other’s borders. The MRA is designed to create efficiencies between the regulators to avoid duplicating inspections enabling the “reallocation of resources towards inspection of drug manufacturing facilities with potentially higher public health risks across the globe.” It’s a good start. Replicating similar agreements across the world to standardize and reciprocate vaccine and therapeutic regulatory approvals would go a long way in eradicating barriers to access the most innovative and lifesaving products.

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73. FDA Commissioner, “Mutual Recognition Agreement (MRA).”
74. Ibid.
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