THE BIOPHARMACEUTICAL INDUSTRY IS LEADING THE WAY IN DEVELOPING NEW VACCINES AND TREATMENTS FOR COVID-19

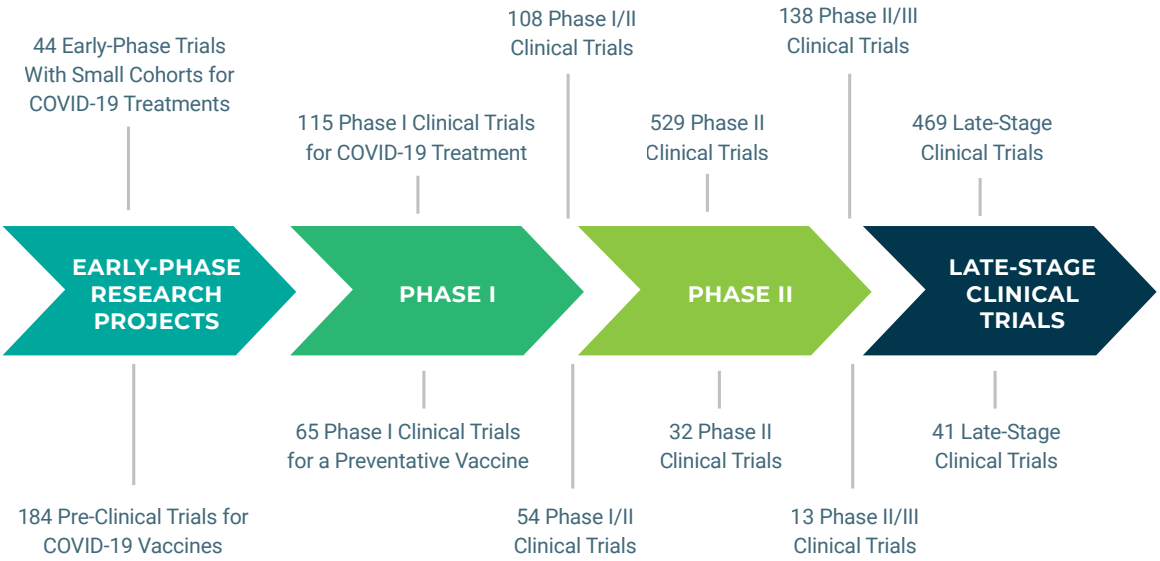
America's biopharmaceutical companies are developing solutions to help diagnose, treat and prevent COVID-19. The biopharmaceutical industry has been responding rapidly to the COVID-19 pandemic and has a long track record of developing solutions to combat a range of infectious diseases and brings deep scientific expertise from decades of working with similar viruses such as MERS, SARS and influenza.

Over the past several decades, PhRMA members have invested billions of dollars in the manufacturing infrastructure and critical technological advances which have allowed us to accelerate vaccine development, identify and bring promising treatment options forward and quickly manufacture new vaccines and treatments for patients.

As of May 3, 2021, there are **1,805 clinical trials testing COVID-19 treatments and vaccines.**[i] This innovation has been ongoing since the genetic sequence of COVID-19 was first released and today we are seeing:

- 1,600 clinical trials for COVID-19 treatments
- 205 clinical trials testing vaccines
- Almost 405 of these clinical trials taking place in the United States

Some of the trials are being conducted in multiple countries simultaneously with the most impactful biopharmaceutical company trials requiring significant investment. The rapid escalation of trials is a testament to robust collaboration, biopharmaceutical investment and the participation of thousands of clinical trial volunteers from all walks of life.



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RESEARCHING AND DEVELOPING POTENTIAL COVID-19 TREATMENTS

PhRMA member companies have been scrutinizing inventories of existing research portfolio libraries of experimental medicines to identify potential treatments for investigation and use to treat COVID-19. In addition, biopharmaceutical research labs have been identifying novel "purpose-built" molecules and treatments such as new monoclonal antibodies to provide additional treatment options. These treatments are directed at blocking or disabling the virus itself, and also for treating secondary clinical manifestations of COVID-19.

PhRMA members also have been manufacturing millions of doses of investigational and previously approved medicines, which may have potential to treat coronavirus, for use in clinical trials around the globe, including compounds formerly tested on other viral pathogens such as Ebola and HIV. These investigational treatments are designed to both stop the virus from attacking the body as well as to treat secondary conditions caused by the virus, such as bacterial infections.

There are currently **more than 545 unique treatments** being tested globally for COVID-19 and COVID-19 related complications.

The chart below shows the phases of development for current COVID-19 treatments.[ii] When analyzing the 990 active clinical trials, a little more than half (57%) are targeting the virus directly, while the rest of the trials focus on related effects of COVID-19 such as pneumonia. Of the 990 active clinical trials, nearly 1,000 trials are testing medicines previously approved for another indication, such as antiviral combinations, and 260 trials are testing novel compounds.[iii] There have been **five treatments, including two monoclonal antibodies**, and one approved antiviral, that have received emergency use authorization (EUA) or approval for COVID-19 from the U.S. Food and Drug Administration (FDA).[iv]

COVID-19 Treatments in Development by Phase
(as of May 3, 2021)

Early Clinical Research	Phase I	Phase I/II	Phase II	Phase II/III	Late-Stage Clinical Trials	FDA/EUA Approval
31	77	72	264	83	193	6

MONOCLONAL ANTIBODIES TO FIGHT COVID-19

The immune system relies on antibodies to detect and destroy harmful substances. After discovering a potential invader—such as a virus, bacteria or fungus—the human body produces antibodies that attach to a part of the invader (usually a protein on its surface), which is called an antigen. Once an antibody binds to an antigen, it acts as a signal to other cells in the immune system to attack and destroy it.

The two monoclonal antibody treatments for which the FDA issued an EUA in 2020 and 2021, mimic the function of our immune system to help fight COVID-19 by blocking the ability of the coronavirus to attach and enter human cells. The virus must enter the cells to reproduce, as it cannot replicate on its own. By preventing it from doing so, these treatments—both of which are a combination of two antibodies—may help slow the spread of a person's infection, potentially reducing the length and severity of symptoms.

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RESEARCHING AND DEVELOPING VACCINES FOR COVID-19

Although the COVID-19 associated virus was only identified in December 2019, biopharmaceutical research companies have already made unprecedented progress developing vaccines of multiple different types. Two mRNA vaccines and one viral vector vaccine have received an EUA from the FDA and are being administered.

Vaccines train a person's immune system to recognize a pathogen such as the virus that causes COVID-19 and neutralize it before it can harm the body. Several PhRMA members are researching vaccine candidates for prevention and collaborating to share existing technologies that can be leveraged to allow rapid upscale of production once successful vaccine candidates are identified.

COVID-19 vaccines are undergoing extensive clinical safety and efficacy testing and must complete successful clinical trials before receiving regulatory approval. In the case of COVID-19 vaccine development, biopharmaceutical companies are using novel techniques to advance vaccine research at a faster pace than has ever been done before.

There are currently 250 clinical trials underway to test **92 vaccine candidates**. The 250 trials in Phase I, Phase II and Phase III that are collectively enrolling over 1.3 million patients. Additionally, there are 184 preclinical studies ongoing for vaccine candidates, with many looking to move into Phase I human clinical trials later this year. Biopharmaceutical researchers are working on further numerous vaccine approaches to ensure adequate supply and fit different patient needs.

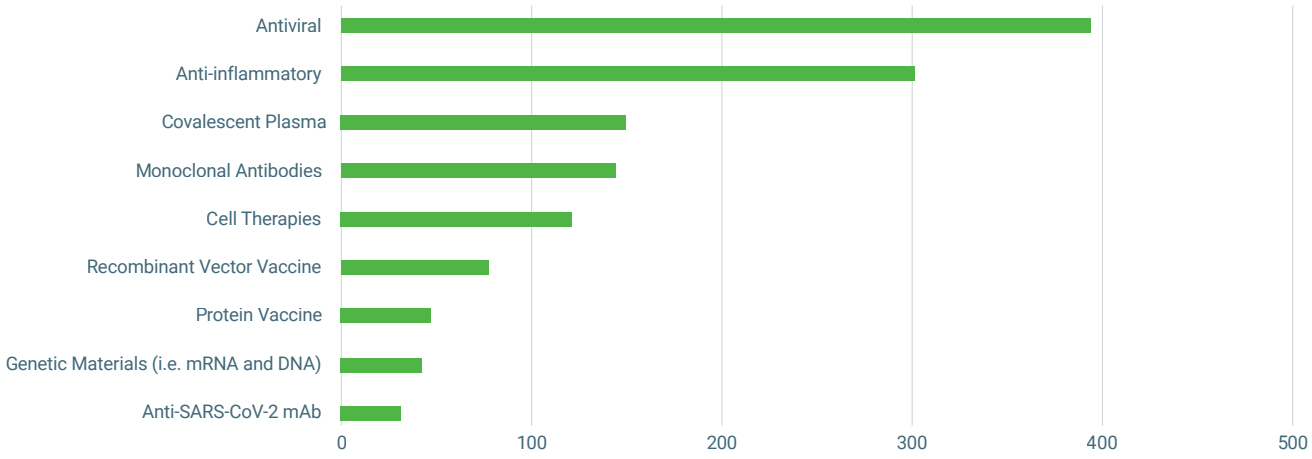
Continued progress has been made with the 92 vaccines already in clinical trials[v]. Companies are also using ingredients that act as an "adjuvant" that can boost the body's immune system response to the vaccine while requiring a smaller dose. This can help companies more quickly scale up production of vaccines once they are approved for use by the broader public.

TRACKING EMERGING VARIANTS

Viruses are constantly changing, which can lead to genetic variations (commonly referred to as variants or mutations) that may have different characteristics both positive and negative. Importantly, not all variants are created equal. Some variants may spread easier or cause more severe disease. Across the industry, companies are tracking variants using genomic surveillance to identify and decode changes in the virus, as well as further continuing clinical research to assess whether modifications or boosters are warranted to existing vaccines to address emerging variants.

MEDICINES AND VACCINES IN DEVELOPMENT FOR COVID-19

Number of Unique Clinical Trials for Therapies and Vaccines in Development for COVID-19 by Type
(as of May 3, 2021)



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"We always need a pharmaceutical partner. I can't think of a vaccine, even one in which we've put substantial intellectual and resource input, that was brought to the goal line without a partnership with industry. So this is a very natural process that we're doing right now…. I have not seen in my experience situations in which we were involved in the development of a vaccine, particularly for low- and middle-income countries that really needed it, where the pharmaceutical companies priced it out of their reach."

— NIAID Director Dr. Anthony Fauci (February 27, 2020)

MANUFACTURING AND DISTRIBUTION AND PARTNERSHIPS

While the vaccines and therapeutics are going through clinical studies, biopharmaceutical researchers are also developing the manufacturing methods to produce therapeutics and vaccines proven safe and effective. Particularly for vaccines[vi] used in large populations, these methods then undergo massive scale up to ensure the manufacture of what can be many millions of doses. This is an enormous undertaking, as the transition from laboratory to manufacturing facility is incredibly complex and the industry must ensure consistency in the vaccine composition and safety and efficacy profiles. As developing the manufacturing strategy is an ongoing process, biopharmaceutical companies are already seeking to expand their manufacturing capacity and enhance the formulation of products. Companies are also initiating manufacturing capabilities at risk in parallel with clinical development, well before a COVID-19 vaccine receives regulatory authorization or approval, to speed the delivery of approved/authorized products to the patients who need them.

Safely delivering a vaccine to patients around the world is an equally challenging undertaking, especially in less developed regions, as vaccines often require special handling, such as temperature control, during distribution. Biopharmaceutical companies are working closely with local governments and NGO partners to lay the groundwork for potential distribution at global scale.

Finally, COVID-19 has demonstrated the importance of having global, innovative, cross-stakholder partnerships. Armed with experience garnered from previous outbreaks and decades of knowledge about infectious diseases, America's biopharmaceutical companies have joined forces to fight COVID-19. Companies are leading by collaborating with each other and key health stakeholders on efforts to address the global health crisis through developing diagnostics, treatments and vaccines to help save lives and restore the rhythms of daily life for billions of people.

The biopharmaceutical industry continues to establish partnerships, enabled by intellectual property protections, licensing agreements and the infrastructure the industry has developed over decades, aimed at boosting capacity to keep pace with global demand so that vaccines make it to those in need as quickly as possible.

The biopharmaceutical industry is committed to developing solutions to address this global public health emergency just as it has in the past. PhRMA member companies not only bring decades of expertise in infectious diseases, including other strains of coronavirus but bring the infrastructure and technologies to allow us to quickly advance potential vaccine and treatment candidates to clinical trials and have the manufacturing capabilities and expertise to allow for quick scale-up.

To date, over one billion vaccines have been administered worldwide, a remarkable scientific and logistical achievement. While this progress should be applauded, biopharmaceutical research companies are not done fighting COVID-19 and won't stop until we beat the virus.

[i] Analysis of publicly available databases such as cilnicaltrials.gov, AdisInsights and the World Health Organization's International Clinical Trials Registry Platform (WHO ICTRP) as of May 3, 2021
[ii] Treatments in development by phase as of May 3, 2021. Note – some medicines may be in two different phases at the same time.
[iii] https://www.gilead.com/purpose/advancing-global-health/covid-19/about-veklury
[iv] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs
[v] Clinical trial data as of May 3, 2021
[vi] https://innovation.org/diseases/infectious/coronavirus/how-scientists-plan-to-develop-coronavirus-vaccine