

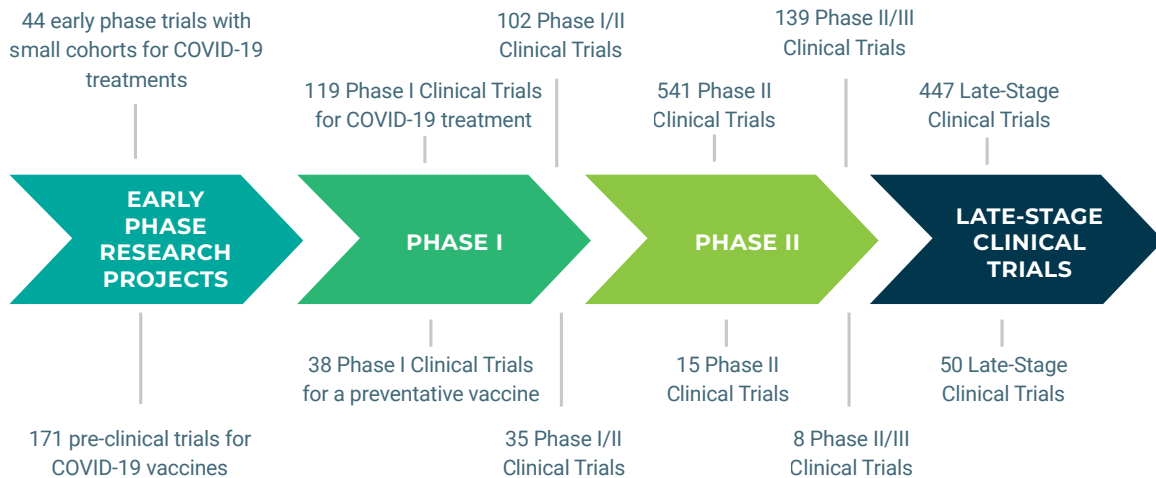
THE BIOPHARMACEUTICAL INDUSTRY IS LEADING THE WAY IN DEVELOPING NEW VACCINES AND TREATMENTS FOR COVID-19

America’s biopharmaceutical companies are developing solutions to help diagnose, treat and prevent COVID-19, the disease caused by a novel strain of coronavirus called SARS-CoV-2. 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.

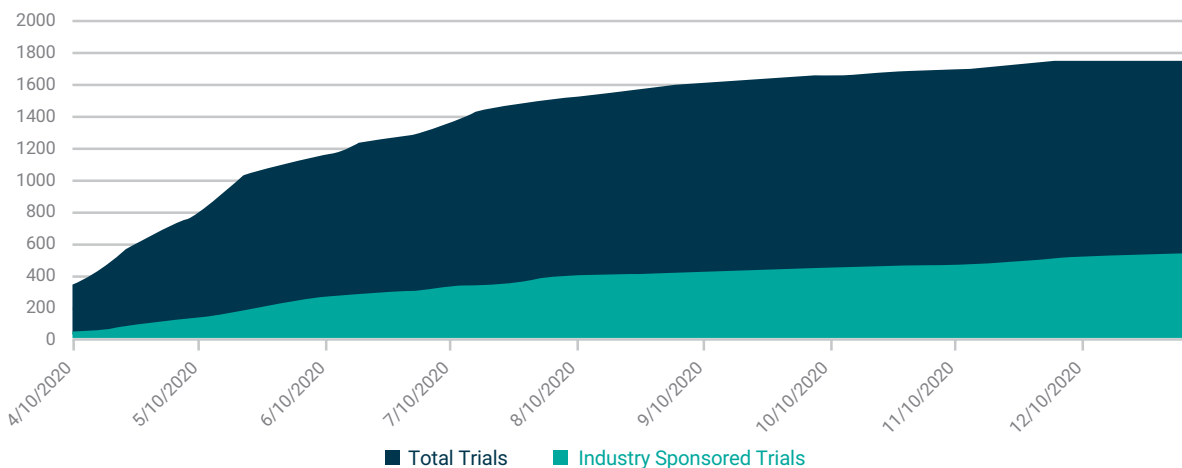
Over the past several decades, PhRMA members have invested billions of dollars in building the manufacturing infrastructure and developing critical technological advances which have allowed us to accelerate vaccine development, identify and rapidly advance promising treatment options and quickly manufacture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

As of January 8, 2021, there are **over 1,750 clinical trials testing COVID-19 treatments and vaccines.**¹ Sponsors are trying a variety of approaches, including nearly 1,600 clinical trials for COVID-19 treatments and 160 clinical trials testing vaccines, with almost 420 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 thanks to the participation of thousands of clinical trial volunteers from all walks of life.



GROWTH OF CLINICAL TRIALS OVER TIME



RESEARCHING AND DEVELOPING COVID-19 TREATMENTS

Across PhRMA's membership, companies scrutinized 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 **560 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 active clinical trials, of the 1,596 active clinical trials, a little more than half (52%) are targeting the virus directly, while the rest of the trials focus on related effects of COVID-19 such as pneumonia. Of the 1,596 active clinical trials, almost 1,000 trials are testing medicines previously approved for another indication, such as antiviral combinations, and over 400 trials are testing novel compounds.ⁱⁱⁱ There have been **5 treatments, including 2 monoclonal antibodies**, that have received emergency use authorization (EUA) for COVID-19 from the FDA.^{iv}

COVID-19 Treatments in Development by Phase
(as of January 8, 2021)

Early Clinical Research	Phase I	Phase I/II	Phase II	Phase II/III	Late-Stage Clinical Trials	FDA EUA
31	78	68	264	82	119	5

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 first two monoclonal antibody treatments for which FDA issued an EUA in 2020, 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—one of which is a single monoclonal antibody, while the other is a combination of two antibodies—may help slow the spread of a person's infection, potentially reducing the length and severity of symptoms.

RESEARCHING AND DEVELOPING VACCINES FOR COVID-19

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.

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 have received an EUA from the U.S. Food and Drug Administration and are being administered pursuant to CDC guidelines.

COVID-19 vaccines are undergoing extensive clinical safety and efficacy testing and must complete successful clinical trials before receiving regulatory approval. In the case COVID-19 vaccine development, biopharmaceutical companies are using

novel techniques to advance vaccine research at a faster pace than has ever been done before.

Continued progress has been made with 64 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.

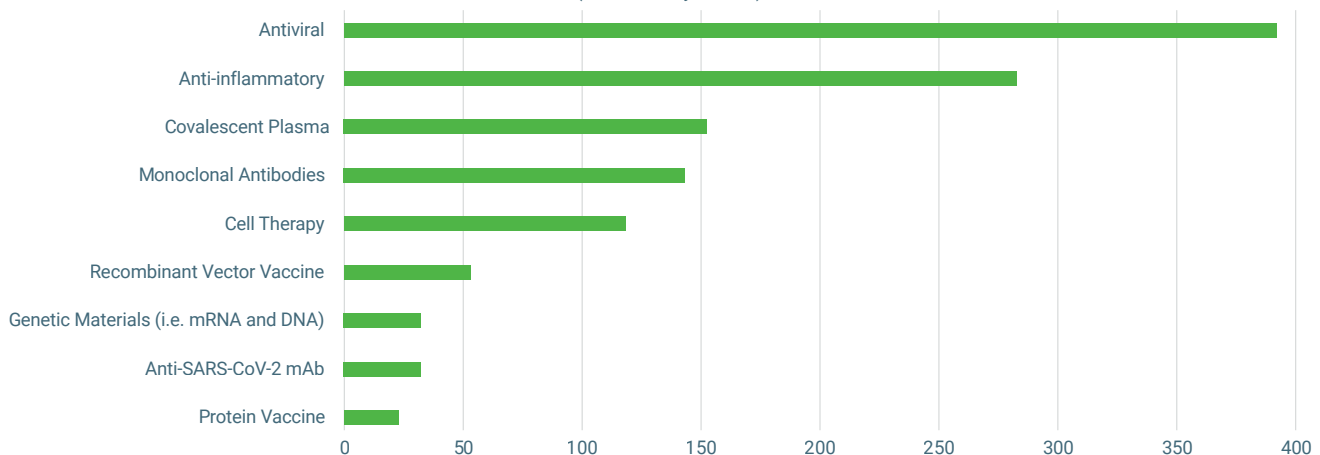
There are currently 160 clinical trials underway to test **64 vaccine candidates**. There are 146 trials in phase I, phase II and phase III that are collectively enrolling over 618,078 patients. Additionally, there are 171 preclinical studies ongoing for vaccine candidates, with many looking to move into Phase I human clinical trials later this year. Biopharmaceutical researchers are working on numerous vaccine approaches to ensure adequate supply and fit different patient needs.

“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)

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 January 8, 2021)



BIOPHARMACEUTICAL INDUSTRIES' LESSONS LEARNED FROM PAST PUBLIC HEALTH EMERGENCIES

The rapid pace at which researchers have been able to identify, sequence and understand this novel strain of coronavirus, begin human clinical trials and obtain an EUA by the FDA for multiple treatments and vaccines in less than one year is a testament to the expertise and experience gained by the biopharmaceutical industry from past public health emergencies.

MANUFACTURING AND DISTRIBUTION

While the vaccines and therapeutics are going through clinical studies, biopharmaceutical researchers are also developing the manufacturing methods that will be used 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 enable 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 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.

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.

ⁱAnalysis of publicly available databases such as clinicaltrials.gov, [AdisInsights](https://adisinsights.com), and the World Health Organization's International Clinical Trials Registry Platform (WHO ICTRP) as of Jan 8, 2021

ⁱⁱTreatments in development by phase as of Jan 8, 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>

^vClinical trial data as of Jan 8, 2021

^{vi}<https://innovation.org/diseases/infectious/coronavirus/how-scientists-plan-to-develop-coronavirus-vaccine>