

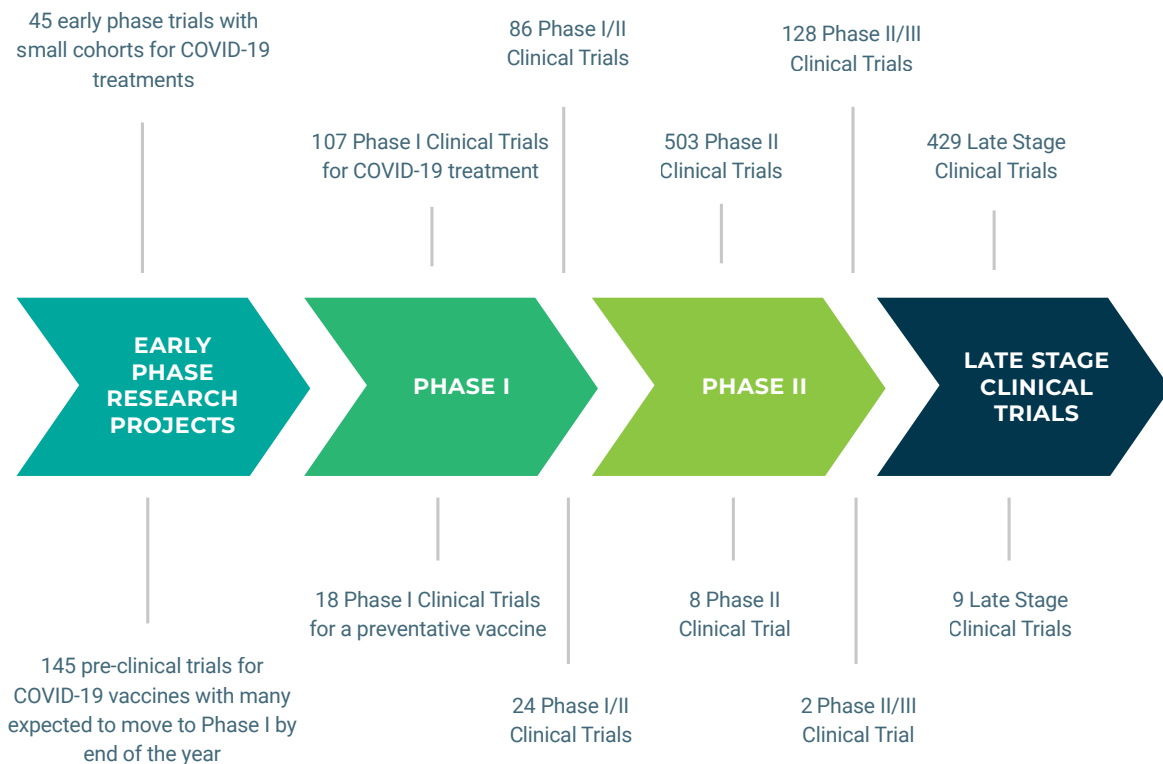
THE BIOPHARMACEUTICAL INDUSTRY IS LEADING THE WAY IN DEVELOPING NEW VACCINES AND TREATMENTS FOR COVID-19

America's biopharmaceutical companies are committed to developing solutions to help diagnose, treat, and prevent COVID-19, the disease caused by a novel strain of coronavirus called SARS-CoV-2. The virus is a new form of coronavirus and appeared in late 2019. The biopharmaceutical industry is responding rapidly to COVID-19 and has a long track record of developing solutions to combat a range of infectious diseases and bring 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 advanced manufacturing infrastructure and developing critical technological advances that will allow us to accelerate vaccine development, identify and rapidly advance promising treatment options and quickly manufacture new vaccines and treatments for patients.

As of September 11, 2020, there are **nearly 1,600 clinical trials testing COVID-19 treatments and vaccines.**¹ Sponsors are trying a variety of approaches, including 1,498 clinical trials for COVID-19 treatments and 99 clinical trials testing a vaccine,

with over 360 of these clinical trials taking place in the United States. Some of the trials are being conducted in multiple countries simultaneously.



RESEARCHING AND DEVELOPING POTENTIAL TREATMENTS

Across PhRMA's membership, companies are scrutinizing inventories of existing research portfolio libraries of experimental medicines to identify additional potential treatments for investigation and use. PhRMA members have also been manufacturing millions of doses of investigational and previously approved medicines that 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 **515 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 1,597 active clinical trials, a little more than half (55%) are targeting the virus directly, while the rest of the trials focus on related effects of COVID-19 such as pneumonia. Of the 1,597 active clinical trials, 955 trials are testing medicines previously approved for another indication, such as antiviral combinations, and over 200 trials are testing novel compounds.ⁱⁱⁱ

COVID-19 Treatments in Development by Phase
(as of September 11, 2020)

Early Clinical Research	Phase I	Phase I/II	Phase II	Phase II/III	Late Stage Clinical Trials
32	71	55	234	74	168

RESEARCHING AND DEVELOPING POTENTIAL VACCINES

Vaccines train a person's immune system to recognize a pathogen such as 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 rapid progress developing potential vaccines. Despite the rapid pace of R&D, vaccines still need to undergo extensive clinical safety testing because they are intended for use in healthy people 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.

Companies are working hard to progress early vaccine research in human clinical trials as soon as possible, shown by the 34 vaccines already in clinical trials.^{iv} 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.

Even with all these scientific advancements, companies and public health officials still predict it will likely take 12 to 18 months at a minimum from the start of human clinical trials before the first vaccine is available.

There are currently 99 clinical trials underway to test **34 vaccine candidates**. There are 50 trials in phase I, phase II and phase III that are collectively enrolling over 100,000 patients. There are also Phase 3 trials testing a previously approved vaccine, mostly in front-line workers, which are aiming to enroll another 330,000 patients. Additionally, there are 145 preclinical studies ongoing for vaccine candidates, with many looking to move into Phase I human clinical trials later this year.

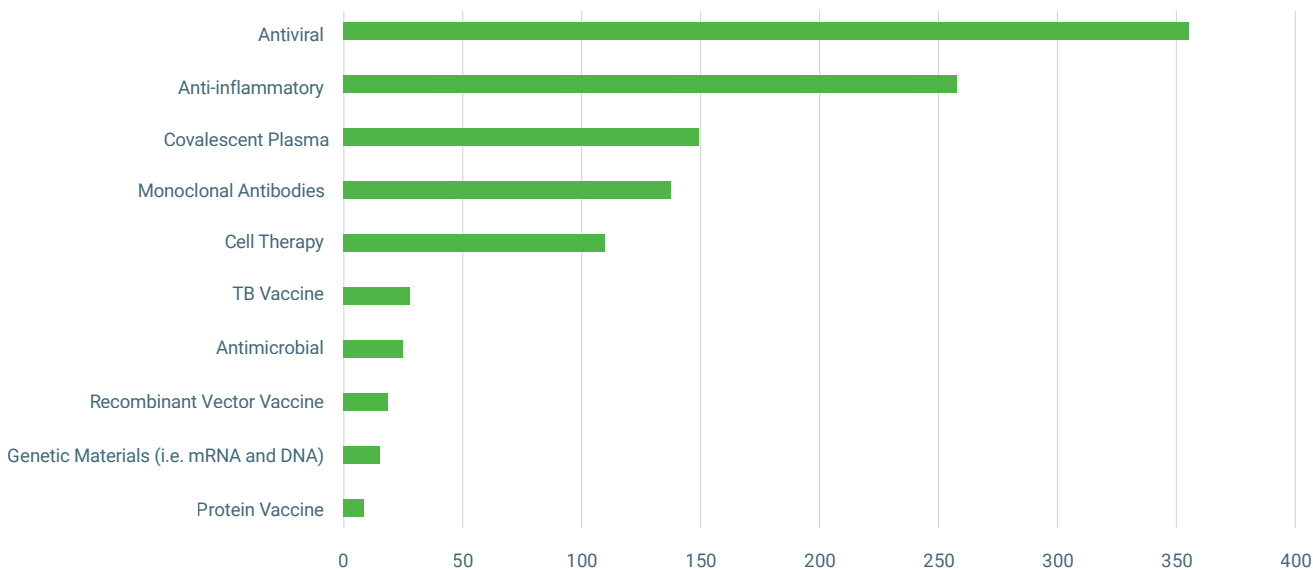
Over the years, biopharmaceutical companies have advanced new technologies that further address safety including better methods of analyzing the interaction of vaccines and the immune system, as well as improved manufacturing capabilities. This means biopharmaceutical researchers have the specialized skills and experience to navigate development successfully, and they understand the pressing need for a safe and effective vaccine to help combat COVID-19.

“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 September 11, 2020)



BIOPHARMACEUTICAL INDUSTRIES' LESSONS LEARNED FROM PAST PUBLIC HEALTH EMERGENCIES

The rapid pace at which researchers have been able to understand this novel strain of coronavirus and get medicines into human clinical trials is a testament to the lessons learned 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. For some types of vaccines¹ 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 can be a multi-year process, biopharmaceutical companies are already seeking to expand their manufacturing capacity. Companies are also initiating manufacturing capabilities at risk, well before a COVID-19 vaccine receives regulatory approval, to speed the production process when a vaccine is ready.

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.

¹Analysis of publicly available databases such as clinicaltrials.gov, AdisInsights, and the World Health Organization's International Clinical Trials Registry Platform (WHO ICTRP) as of September 11, 2020

²Treatments in development by phase as of September 11, 2020. Note – some medicines may be in two different phases at the same time

³<https://www.gilead.com/purpose/advancing-global-health/covid-19/about-remdesivir>

⁴Clinical trial data as of September 11, 2020

⁵<https://innovation.org/diseases/infectious/coronavirus/how-scientists-plan-to-develop-coronavirus-vaccine>