

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.

## 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 emergency use. PhRMA members have also been manufacturing millions of doses of investigational and previously approved medicines that may have potential to treat coronavirus for emergency use and 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.

## RESEARCHING AND DEVELOPING POTENTIAL VACCINES

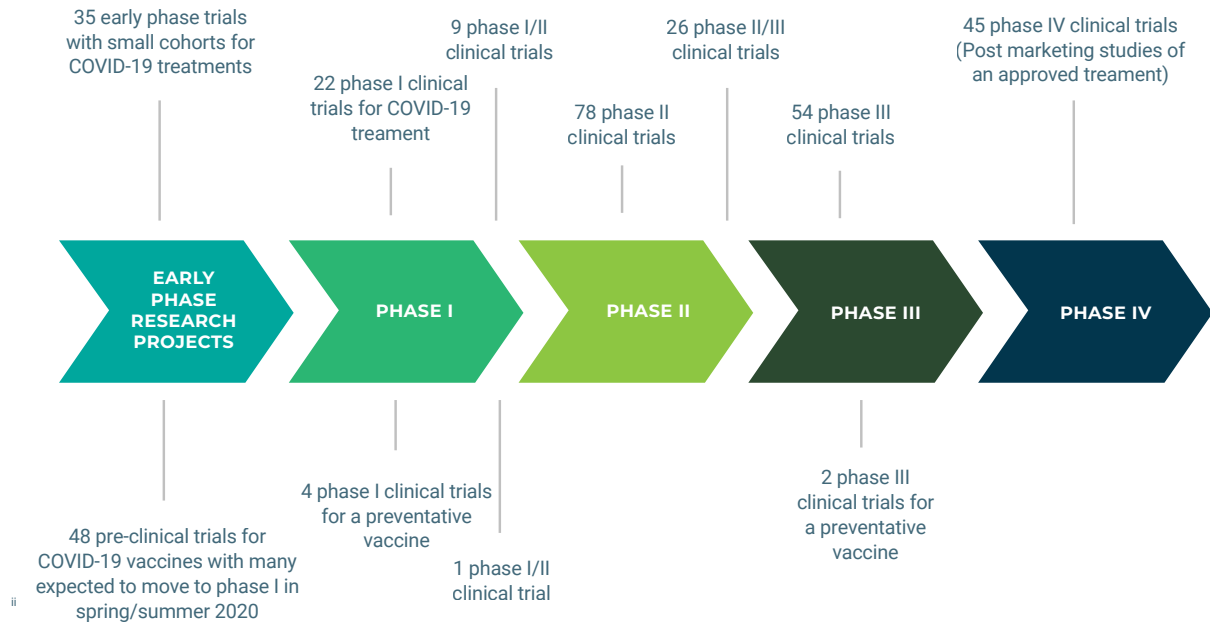
Vaccines train a person's immune system to recognize a pathogen such as COVID-19 and neutralize it before it can harm the body. Several members are researching vaccine candidates for prevention and collaborating to share existing technologies that can be leveraged to allow rapid upscale of production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

Because the COVID-19 strand did not exist prior to December 2019, the vaccines in development for this specific strain of coronavirus are still in early phases of research. Vaccines generally 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 of development of a COVID-19 vaccine,

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, and more than five vaccines are already in clinical trials.<sup>1</sup> 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 before the first vaccine is available.

# THE BIOPHARMACEUTICAL INDUSTRY IS LEADING THE WAY IN DEVELOPING NEW VACCINES AND TREATMENTS FOR 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 Anthony Fauci (February 27, 2020)

## MEDICINES AND VACCINES IN DEVELOPMENT FOR COVID-19

### CLINICAL TRIALS

As of April 8, 2020, there are **310 clinical trials testing COVID-19 treatments and vaccines**.<sup>iii</sup> Sponsors are trying a variety of approaches, including 303 clinical trials for COVID-19 treatments and 7 clinical trials testing a vaccine, with more than 40 of these clinical trials taking place in the United States. Some of the trials are being conducted in multiple countries at the same time.

### TREATMENTS

There are currently **139 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.<sup>iv</sup> When analyzing the active clinical trials, of the 310 active clinical trials, a little more than half (51%) are targeting the virus directly, while the rest of the trials focus on related effects of COVID-19 such as pneumonia. Of the 310 active clinical trials, more than 200 trials are testing medicines previously approved for another indication, such as hydroxychloroquine and antiviral combinations and over 50 trials are testing novel compounds.<sup>v</sup>

**VACCINES**

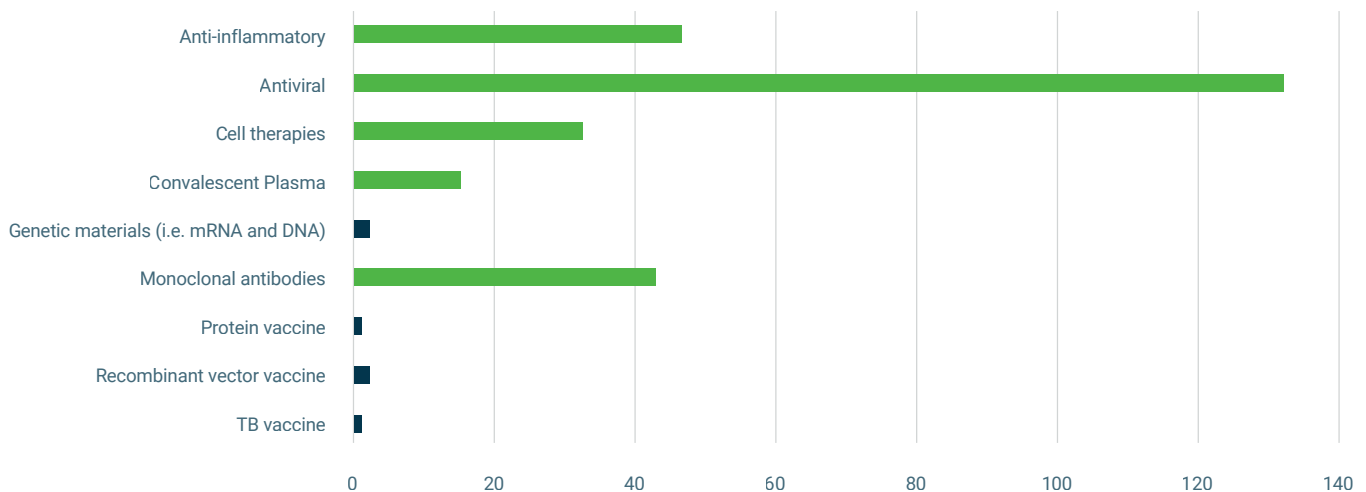
There are currently 7 clinical trials underway to test **six vaccine candidates**. Five phase I clinical trials are collectively seeking to enroll nearly 800 patients, and one of the vaccines previously tested for TB has another 5,700 patients participating in phase 3 clinical trials.

There are also an additional 48 preclinical trials ongoing for vaccine candidates, with many looking to move on to phase I human clinical trials in the spring and summer of this year.

COVID-19 Treatments in Development by Phase  
(as of April 8, 2020)

Early clinical research	Phase I	Phase I/II	Phase II	Phase II/III	Phase III	Phase IV (Post Market Studies)
24	16	8	42	18	30	26

Types of Therapies and Vaccines in Development for COVID-19  
(as of April 8, 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.

**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.**

<sup>1</sup>Clinical trial data as of April 8, 2020

<sup>2</sup>Clinical trial data as of April 8, 2020. Note some clinical trials have unknown phase information, many clinical trials are testing the same treatment candidate.

<sup>3</sup>Analysis of publicly available databases such as clinicaltrials.gov, AdisInsights and the World Health Organization's International Clinical Trials Registry Platform (WHO ICTRP) as of April 8, 2020.

<sup>4</sup>Treatments in development by phase as of April 8, 2020. Note – some medicines may be in two different phases at the same time.

<sup>5</sup><https://www.gilead.com/purpose/advancing-global-health/covid-19/about-remdesivir>