HOW THE BIOPHARMACEUTICAL INDUSTRY HAS RESPONDED TO COVID-19

America's biopharmaceutical companies have successfully researched, developed and delivered multiple vaccines and therapeutics to help halt the spread and effects of COVID-19. While the positive medical and societal impact of these successes has been immense, the industry continues to innovate new ways to diagnose, treat and prevent the virus and long-term complications. The biopharmaceutical industry brings deep scientific and manufacturing expertise from decades of working to combat similar viruses such as MERS, SARS and influenza to its work in fighting the coronavirus.

Once the COVID-19 virus was genomically sequenced, there have been thousands of trials conducted that continue to test new, and improve on now-existing, COVID-19 therapeutics and vaccines.[1] The rapid escalation of trials across the biomedical research and development (R&D) ecosystem is a testament to robust collaboration, biopharmaceutical investment and the participation of thousands of people from all walks of life.

LEADING THE WAY IN VACCINES AND TREATMENTS FOR COVID-19

Researching and developing new treatments and vaccines is a complex and multifaceted process, requiring significant time and resource investment. It can take more than 10 years to develop a novel vaccine from the discovery stage all the way through to approval by the FDA. In responding to the COVID-19 pandemic, biopharmaceutical research companies utilized decades of experience in past infectious diseases and platform technologies alongside innovative clinical trials to dramatically shorten the development timeline for the vaccines.

Since the COVID-19 associated virus was identified in December 2019, biopharmaceutical companies have made unprecedented progress developing vaccines using multiple different scientific approaches. Two mRNA vaccines and one vector-based vaccine have been authorized or approved by the FDA for certain populations – however many other vaccine candidates never made it beyond stages of clinical study – evidence of how difficult it can be to research and successfully develop vaccines. As with any medicinal product, vaccines undergo a comprehensive research process in order to meet rigorous FDA standards for safety and efficacy. All the COVID-19 vaccines authorized or approved by the FDA faced the same standard of regulatory review as other products for such pathways and included representation of clinical trial participants from diverse backgrounds.

As of November 5, 2021, there have been over 8 billion vaccine doses delivered globally.[2] The United States continues to lead in vaccine development and production. Globally, vaccine manufacturers are estimated to produce as many as 12 billion doses of COVID-19 vaccines by the end of 2021, enabled by the hundreds of partnerships and collaborations between manufacturers and stakeholders across the ecosystem.[3]

Additionally, PhRMA member companies scrutinized inventories of existing research portfolio libraries of marketed and experimental medicines to identify potential therapeutics to treat COVID-19. As of this fall, there are hundreds of unique therapeutics that have and continue to be tested globally for COVID-19 and COVID-19 related complications. In addition, biopharmaceutical research labs identified novel "purpose-built" molecules and therapeutics such as new monoclonal antibodies to provide additional treatment options, including antiviral therapies. These therapeutics are directed at blocking or disabling the virus itself or for treating secondary clinical manifestations of COVID-19. Secondary manifestations include those that can be found with long COVID, defined by the CDC as a wide range of persistent symptoms that can last weeks or months after first being diagnosed with the infection and can happen to anyone who has had COVID-19 even if the illness was mild or asymptomatic. The CDC recommends the best way to reduce the number of long COVID cases is to prevent COVID-19, a reminder that vaccines are a key defense against the virus.

[1] 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 June 25, 2021

[2] https://ourworldindata.org/covid-vaccinations?country=OWID_WRL

[3] https://www.ifpma.org/wp-content/uploads/2021/05/airfinity_production_19.05.2021.pdf

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Two types of treatments that target the SARS-CoV-2 virus:

- Monoclonal antibodies (mAb) are synthetic versions of the body's antibodies produced in a laboratory and designed to restore, mimic, or enhance immune system functions. They help by slowing the spread of the virus within the body, which is achieved by blocking the ability of the virus to enter cells, and by reducing potentially harmful inflammation as a result of the infection. As of September 2021, four monoclonal antibodies have been authorized for emergency use by the FDA for the treatment of certain patients with COVID-19, and clinical trials continue for additional monoclonal antibody products.
- Antivirals are molecules specifically created to target the virus directly, disrupting or stopping its ability to replicate and spread. Thus far, the FDA has approved one antiviral for use in certain patients 12 years of age and older requiring hospitalization for the treatment of COVID-19. Hundreds of clinical trials are currently investigating antivirals for COVID-19, including more than a dozen newly developed antivirals specifically designed to target the SARS-CoV-2 virus.

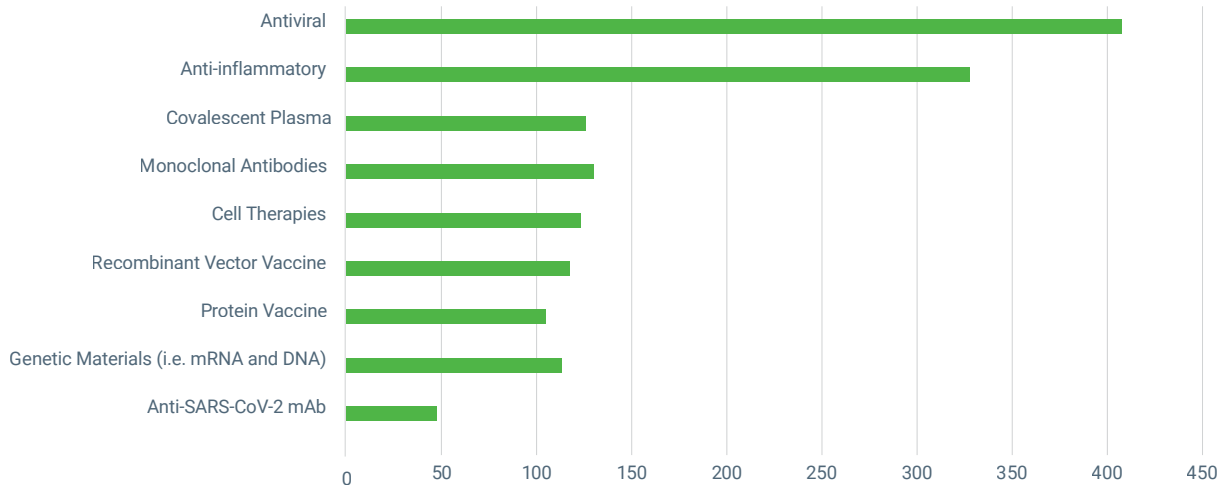
Treatments that are effective in fighting infection across variants – including antivirals and monoclonal antibodies – are a crucial tool to help aid recovery. By preventing the virus from replicating or clearing cells in which the virus has already entered, effective treatments can help slow the spread of a person's infection, potentially reducing the length and severity of symptoms.

TRACKING 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 more easily 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 conducting further 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 November 5, 2021)



MANUFACTURING AND DISTRIBUTION AND PARTNERSHIPS

Biopharmaceutical researchers have developed the critical, specific manufacturing methods to produce COVID-19 therapeutics and vaccines. Particularly for vaccines used in large populations, these methods are then scaled up to produce 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 and quality of the vaccine throughout scale-up. As developing the manufacturing strategy is an ongoing process, biopharmaceutical companies are continuing to seek to expand their manufacturing capacity. Companies also initiated manufacturing capabilities at risk in parallel with clinical development, for example, well before a COVID-19 vaccine received 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 delivery and handling, such as temperature controls. Biopharmaceutical companies are working closely with local governments and NGO partners to deliver and distribute vaccines at global scale.

THE BIOPHARMACEUTICAL RESEARCH ECOSYSTEM RESPONDING TO COVID-19

COVID-19 has demonstrated the importance of having global, innovative, cross-stakeholder partnerships. Armed with experience garnered from previous outbreaks of 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 with key health stakeholders on efforts to address the global health crisis through developing diagnostics, therapeutics and vaccines to help save lives and restore the rhythms of daily life for billions of people.

The biopharmaceutical industry continues to establish partnerships, facilitated in part by the strong U.S. intellectual property (IP) policy framework, licensing agreements and the collaborative infrastructure the industry has developed over decades. It is this IP framework that fosters the collaborations that are helping to boost manufacturing capacity to meet global vaccination needs.

Some critics have claimed that the success in the COVID-19 response is solely because the National Institutes of Health (NIH) use public funds to discover new therapies which are then handed off to biopharmaceutical companies. The reality is that the COVID-19 therapeutics and vaccines are the result of decades of private sector investments in infectious disease, new technology platforms, and vaccine and therapeutics research. As FDA Acting Director Janet Woodcock has stated, "Although NIH understands and contributes to the science of how to evaluate various therapeutic candidates, it does not have the expertise to develop individual products. The NIH enterprise is necessary [for the advancement of product development] but it is not sufficient."

"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)