The Biopharmaceutical Industry's Efforts to Beat Coronavirus

Pennsylvania House Health Committee

Sharon Lamberton, MS, RN, PhRMA

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Our Commitment to *Beat* Coronavirus

We **are rapidly screening our vast global libraries of medicines** to identify potential treatments and have numerous clinical trials underway to test new and existing therapies

We are **dedicating our top scientists and using our investments in new technologies** to speed the development of safe and effective vaccines

We are **sharing the learnings from clinical trials in real time** with governments and other companies to advance the development of additional therapies

We are **expanding our unique manufacturing capabilities and sharing available capacity** to ramp up production once a successful medicine or vaccine is developed

We are **collaborating with government agencies, hospitals, doctors and others** to donate supplies and medicines to help those affected around the world

We are **working with governments and insurers** to ensure that when new treatments and vaccines are approved they will be available and affordable for patients

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Factors Contributing to the Industry's Response

Armed with experience garnered from previous outbreaks and a vast storehouse of knowledge about infectious diseases like influenza, malaria and HIV, researchers are working to develop and deliver diagnostics, treatments and vaccines to save lives and restore the rhythms of daily life for billions of people.

DIAGNOSTICS

It's essential to know who has been infected.

- Companies are accelerating the development of diagnostic testing capabilities to scale-up screening and working in partnership with governments and diagnostic companies on existing screening programs to supplement testing.

EXISTING MEDICINES

Medicines approved for other diseases may have some benefit for patients with COVID-19.

- Researchers are testing antivirals, antibiotics and other medicines.
- These medicines have the potential to reduce the burden of COVID-19 on hospitals by reducing the length and severity of disease.

NEW TREATMENTS

Various drugs are in development, with some entering human trials.

- Researchers are working on new antiviral medications to interfere with ways the virus infects cells and reproduces.
- Antibody-based drugs may be able to mobilize the immune system against the virus.

VACCINES

A vaccine would provide a preventive approach to beating COVID-19.

- Although vaccines can take longer to develop than other treatments, once enough people in a community are vaccinated, individuals are protected and the community risk of transmission is reduced. A variety of biopharmaceutical companies are taking different approaches to find a vaccine. More "shots on goal" will significantly increase the chances of success.

MANUFACTURING

We are committed to manufacturing these medicines and making them available to those who need them.

- We're ramping up output of existing medicines with demonstrated benefit and investing in infrastructure to accelerate production of new treatments.
- Biopharmaceutical companies are planning and building manufacturing capacity without assurance medicine and vaccine candidates will ultimately be successful, to ensure that if one is, distribution can occur rapidly.
- America's biopharmaceutical companies are ensuring that solutions can be made available quickly to everyone who needs them.

Developing Treatments and Vaccines to Fight COVID-19

There are **1649 clinical trials under way across the globe** for vaccinations and treatments.

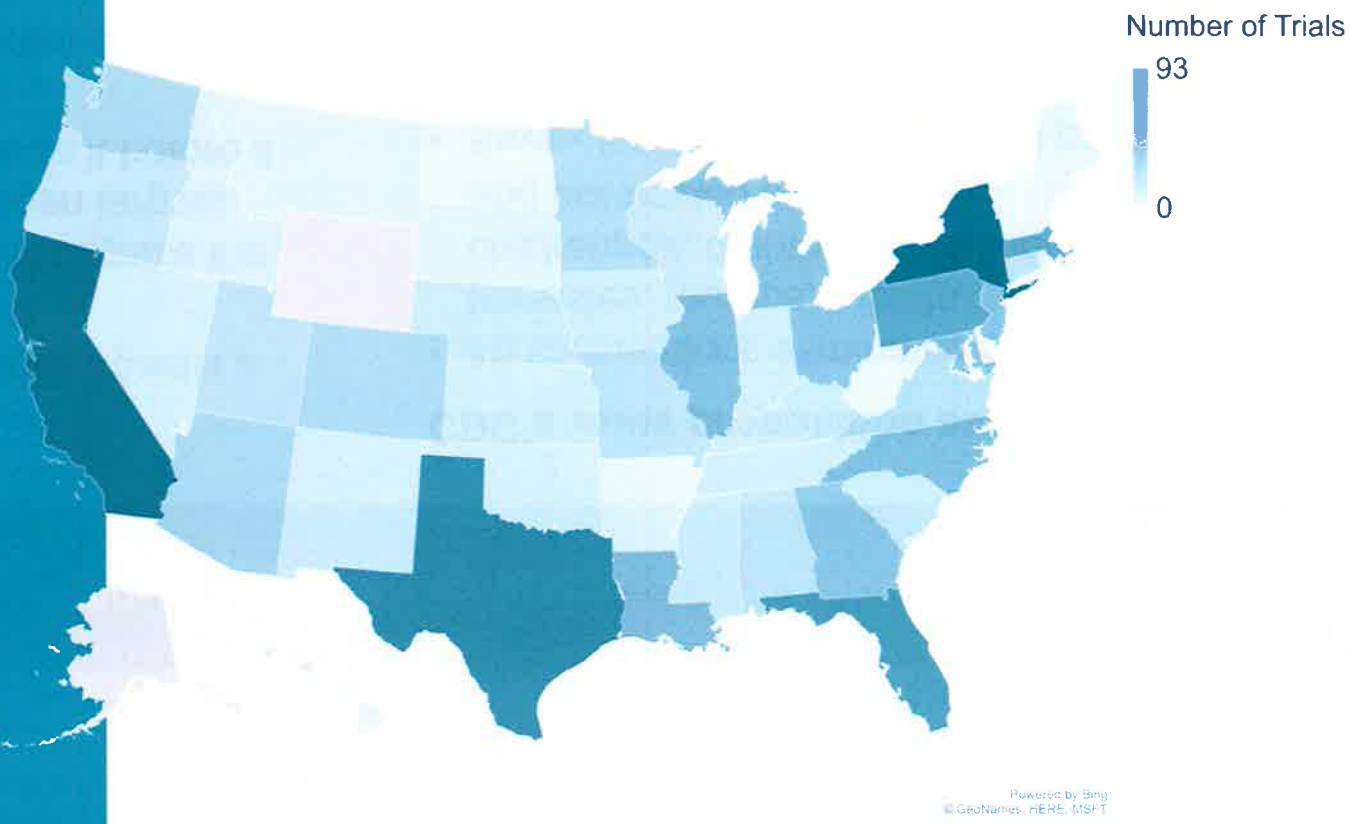
Data as of 10/09/2020

Source: World Health Organization International Clinical Trials Registry Platform (ICTRP)

U.S. Clinical Trials of Investigational Therapies

There are 352 clinical trials investigating therapeutics in 46 states and Washington, D.C.

119 of the 352 clinical trials are being conducted in more than one state



Data as of 9/04/2020

Source: World Health Organization International Clinical Trials Registry Platform (ICTRP)

Vaccines

What we need to know

What is a vaccine?

- A biologic that provides immunity against a particular disease
- Trains the immune system to recognize the pathogen or other protein/antigen targets causing a disease and neutralize it before it harms the body
- Can be developed using different scientific approaches
- Takes 8-10 yrs. on average in R&D/ only 15% succeed

CDC's value proposition over 20 years

- 16 vaccinations eliminated several diseases (measles, mumps, rubella, polio, chickenpox, diphtheria, whooping cough); and eradicated smallpox
- Saves $406B in direct medical costs; and $1.9T in total societal costs
- Prevents 936K deaths & 8M hospitalization
  - Hep C example
    - $50 injection vs. $750K liver transplant

Challenges Associated with Vaccine R&D

1) **Scientific Challenges**
   - Identifying/sequencing the exact strain of the virus in order to create/test a vaccine
   - Understand the disease and how the immune system reacts

2) **Clinical Trial Challenges**
   - Healthy volunteers for clinical trials
   - Identifying sufficiently diverse populations for volunteers
   - Large trials needed to demonstrate safety, efficacy

3) **Manufacturing and Distribution Challenges**
   - Complexity of vaccine manufacturing process
   - Packaging, storage and delivery/transportation of the vaccine including cold storage

It Will Take a Minimum of 18 to 24 Months for Potential FDA Approval of a COVID-19 Vaccine

Faster Timeline

- **This is significantly less time than it has taken for previous vaccine development programs**
  - In 2003, it took 20 months from sequencing SARS to the first human study of a vaccine
  - Today, it has been less than 4 months from sequencing SARS-CoV-2 to the first human study of a vaccine

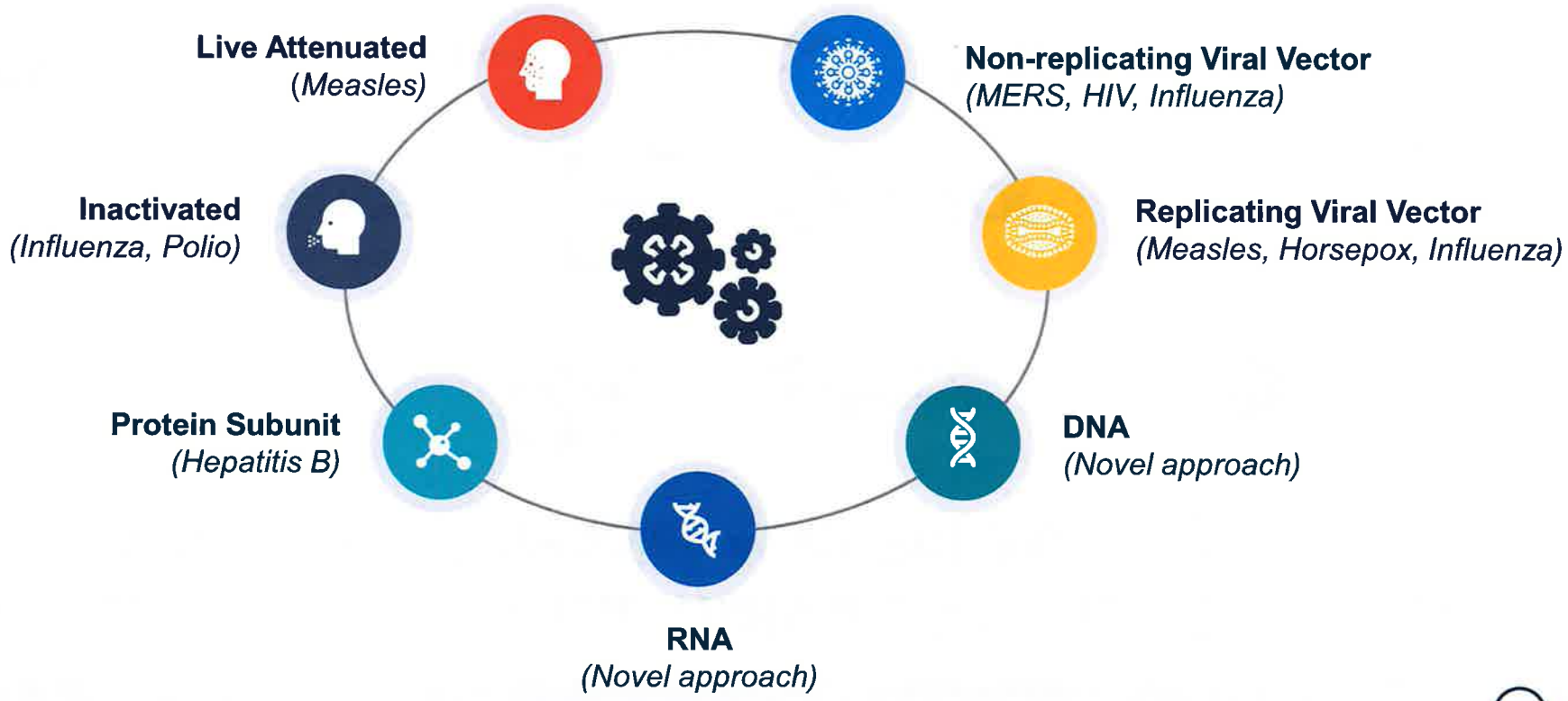
Differing Approaches

- **Some approaches offer speed**
  - Knowing the virus's genetic sequence, companies can synthesize and scale up production of a RNA vaccine in a matter of weeks
- **Some approaches can boost the impact of a potential vaccine**
  - Adjuvants can boost the immune response and minimize the amount of vaccine needed

Failure Rate

- **There is a high failure rate**
  - Only 5-10% are likely to succeed
  - We need lots of shots on goal

Using Many Approaches to Develop Vaccines



Source: World Health Organization International Clinical Trials Registry Platform (ICTRP)

Hundreds of these Clinical Trials are Testing 135 Unique Investigational Therapies from PhRMA Members

Data as of 9/04/2020

Source: World Health Organization International Clinical Trials Registry Platform (ICTRP)

Clinical & Preclinical Stage Vaccine Pipeline

Supported by BARDA / DoD

Jointly developed

Source: Biomedtracker, Biocentury, BIO Industry Analysis

1. PrEP Biopharm vaccine dsRNA, all others mRNA

Oxford, Astrazeneca: ChAdOx1. Symvivo: bacTRL-Spike. Baylor College: BCG tuberculosis vaccine.

Sinopharm with two vaccines in phase 1 trials (one beginning Apr 12 the other Apr 27)

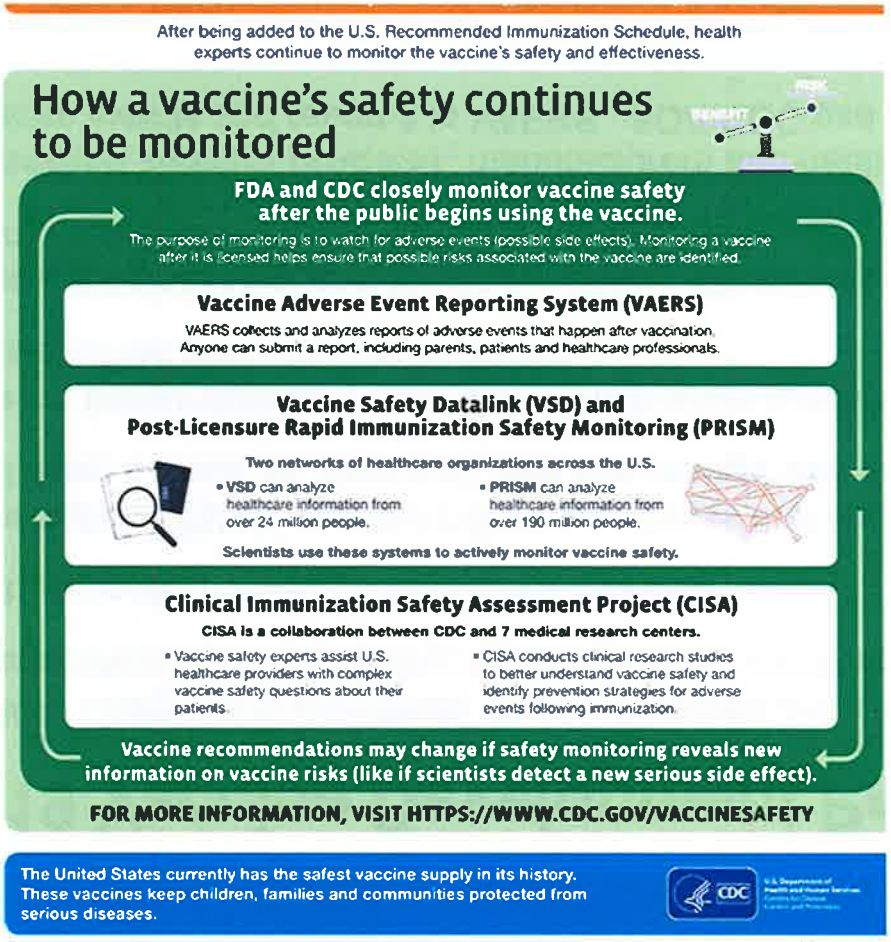
Bio Biotechnology Innovation Organization

Info as of Sept 28, not exhaustive

How Has the Vaccine Timeline Been Shortened?

1) We built on knowledge from previous viruses (SARS, MERS, Zika, Ebola).
2) We invested billions into new technology that shortens time it takes to decode viruses and develop new vaccines.
3) We started to scale up and manufacture millions of doses, even before FDA approval.
4) Industry is working to enhance enrollment of diverse participants in clinical trials.
5) Industry is working with patient groups to encourage greater participation and educating on rigorous safety requirements for FDA approval.
6) Operation Warp Speed (OWS) created to identify the most promising candidates to advance through clinical trials.

The Safety of Vaccines Is Monitored Through Multiple Systems



COVID-19 Vaccine Development Process

1. **Operation Warp Speed (OWS):** designed to accelerate the development and distribution of COVID-19 vaccines, treatments, and diagnostics; $12B in funding; to deliver 300M vaccines by January 2021
2. **Research and development:** expedited development (12-24 months)
3. **FDA Emergency Use Authorization (EUA):** granted if FDA determines that known/potential benefits outweigh the known/potential risks; it is not an "approval" and can change with emerging new evidence
4. **CDC's Advisory Committee on Immunization Practices (ACIP):** gives recommendations for coverage, reimbursement to plans and states/fed govt, standards of care
5. **National Academy of Science, Engineering and Medicine (NASEM):** creates a roadmap of who should get vaccine (equitable distribution)
6. **Vaccine Adverse Event Reporting System (VAERS):** manufacturers and healthcare providers are required to monitor post approval adverse events and report it to VAERS. FDA/CDC use this data to assess possible safety signals.
7. **CDC's Immunization Safety Office (ISO)** monitors and determines if health problems are possibly related to a vaccine.
8. **CDC/DOD**: will support distribution of COVID vaccines to the states

"Science First" Movement to Counter Public Perception:

Public opinion shows 42% doubt safety of immunizations (previously, average is 25%)

Pledge by Nine PhRMA Member Company CEOs

- Safety is the top priority
- Will continue to adhere to high scientific and ethical standards in clinical trials
- Submission for approval ONLY after demonstrating safety and efficacy
- Ensure sufficient supply and range of vaccine options

Similar messages published by NIH Institute Directors, FDA Center Directors

BIO Open Letter

- Encourages disclosures of clinical data
- FDA gold-standard regulatory body- held to the highest scientific and medical integrity
- Data-driven new products

PhRMA Statement:

- Committed to highest standards in R&D
- Must include diverse populations
- Allocation/distribution process should be transparent

Ensuring Continuity in the Medicine Supply Chain

Biopharmaceutical Companies

- **Companies report substantial data on certain types of potential shortages to FDA** and they work closely with the agency to prevent and mitigate shortages
- **Companies have robust inventory management systems** that typically include:
  - Data on anticipated demand reflecting historical demand and supply data
  - Risk management plans that address additional or alternate manufacturing sites, inventory reserves, and/or a range of global external suppliers
  - Logistics planning to ensure continuity in shipping of supplies

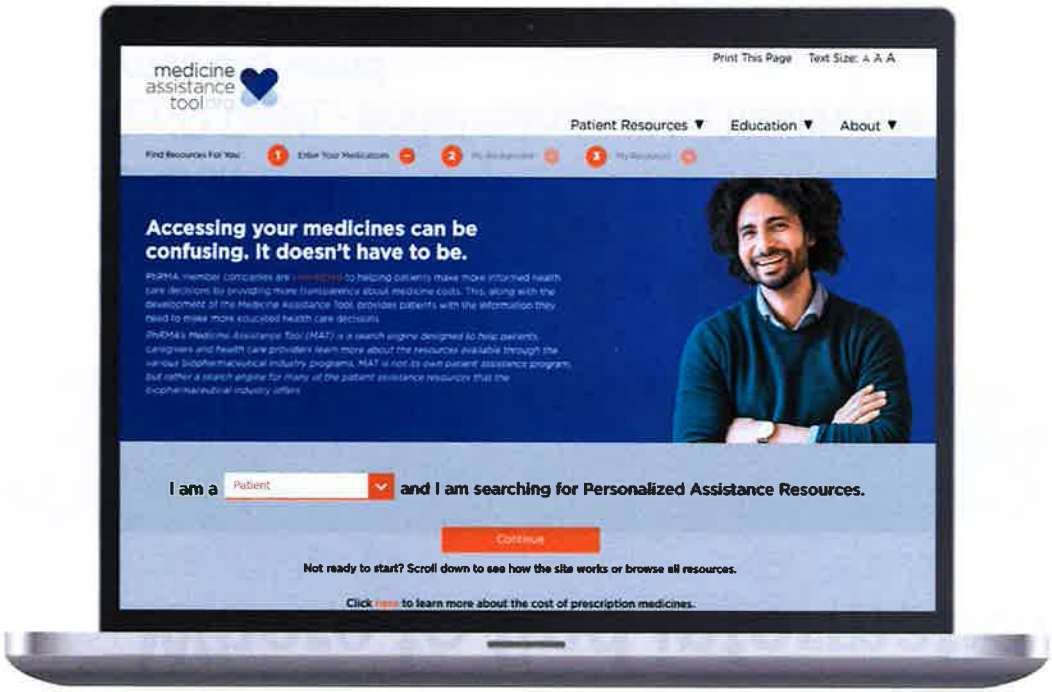
U.S. Food and Drug Administration

- **FDA is working with individual companies to facilitate ramping up manufacturing** to address surges in demand and expediting approvals of changes in the drug supply chain
- **FDA is working closely with companies to expedite development and availability of COVID-19 treatments and vaccines**, including helping companies to leverage scientific and clinical trial data from the United States and other countries

Where to find information on clinical trials?

- Clinicaltrial.gov - is a database of privately/publicly funded clinical studies around the world
- NIAID's Covid 19 Prevention Network - provides clinical trial information, treatment, and clinical research
- COVID Dash - portal managed by healthcare professionals to encourage people to volunteer across the world
- NIH COVID-19 Prevention Network - provides locations to volunteer, information on clinical trials
- Center Watch - provides patient resources, professional resources, trial listings
- WHO tracker

Many of America's Biopharmaceutical Companies Are Expanding Their Assistance Programs To Help More People



950+ public and private programs

The Medicine Assistance Tool (MAT) is a web platform designed to help patients, caregivers and health care providers learn more about some of the resources available to assist in affording their medicines.

www.MAT.org

MAT Can Help Patients Learn More About Their Medicine Costs

PhRMA member companies are committed to helping patients make more informed health care decisions by providing more transparency about medicine costs. Through MAT.org, we share links to member company websites that include:

List Price of a Medicine

Average Estimated or Typical Patient Out-of-pocket Costs

Other Context About Potential Cost of the Medicine

Each member company has individually and independently determined the content of any cost information provided on their websites.

PhRMA and Healthcare Ready

PhRMA has joined forces with **Healthcare Ready** to facilitate the financial support and in-kind donations of personal protective equipment, medicines, and critical medical supplies.

Examples of requests Healthcare Ready can support include:

- Personal protective equipment
- Medical supplies
- Assistance in helping a constituent fill their prescription

These requests can be made by contacting alerts@healthcareready.org.

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Healthcare Ready Programs for Constituents

Healthcare Ready Resources

RX OPEN: Provides access to open and closed pharmacies in a disaster-stricken area.

RX ON THE RUN: Personalized wallet card to document prescriptions and other important medical information.

COVID-19 Resource Hub: Resources for individuals and patients including state-level insurance emergency orders on prescription refills and telehealth coverage policies for COVID-19, and relevant pandemic business continuity resources.

For More Resources and Information, Visit
PhRMA.org/Coronavirus

- **An up-to-date list of member company efforts to combat COVID-19**
- **A factsheet on the pipeline for new vaccine and treatments**
- **An open letter from PhRMA's CEO and PhRMA's Chairman of the Board**
- **The latest Catalyst blog posts on COVID-19**
- **An infographic on how the industry is fighting COVID-19**

THE BIOPHARMACEUTICAL INDUSTRY'S UNIQUE ROLE IN RESPONDING TO COVID-19

As the outbreak of COVID-19 – a disease caused by a novel strain of coronavirus – evolves in the United States and around the globe, the biopharmaceutical industry is working around the clock to find solutions.

America's biopharmaceutical companies are working tirelessly to develop ways to diagnose, prevent and treat those with coronavirus. These companies are also donating medical supplies, personal protective equipment, existing treatments and medicines, and are providing monetary support to front line response teams.

HERE IS A CLOSER LOOK AT FOUR OF THE KEY WAYS THE BIOPHARMACEUTICAL INDUSTRY IS COMBATTING COVID-19:

1. DEVELOPING POTENTIAL NEW TREATMENTS AND VACCINES

As part of its commitment to finding solutions for patients with COVID-19 and preventing others from becoming infected, PhRMA members have been donating investigational compounds that may have potential to treat coronavirus for emergency use and in clinical trials, including compounds formerly tested on other viral pathogens such as Ebola and HIV.

Companies are also deploying their own clinical trials as quickly as possible to test promising investigational antiviral agents. Other members are researching novel and existing vaccine candidates to identify promising potential medicines that have the ability to protect people from coronavirus infection. Importantly, biopharmaceutical industry research and development programs are pursuing a wide diversity of approaches to the development of treatments and vaccines and are also seeking to reduce the most severe symptoms associated with COVID-19.

The multiple avenues to preventive measures include a variety of vaccine approaches including mRNA and DNA vaccines, vaccines using synthetic materials and therapeutic antibodies that could be used not only to treat COVID-19 but also as a temporary preventive treatment in the absence of a vaccine.

Treatments under investigation include antiviral approaches such as protease inhibitors and nucleotide analogs to slow or reduce viral infections and treatments to reduce the severity of pulmonary manifestations of COVID-19 such as IL-6 inhibitors to reduce the risk of "cytokine storm" and antibacterials and vaccines to reduce the risk of secondary pneumococcal pneumonia. It is not just the number of shots on goal, but also the wide variety of approaches being taken, that optimizes the chances of finding successful ways to treat and prevent this disease.

Companies are also leveraging existing technologies to provide the ability to rapidly upscale production once a potential vaccine candidate is identified. Many companies are already investing heavily to increase production capacity. Similar efforts are underway for small molecule and antibody treatments.

2. ENGAGING WITH PUBLIC PARTNERS TO SHARE KNOWLEDGE

Responding effectively to a public health emergency requires close collaboration between public and private organizations around the world to share insights that could accelerate treatment and prevention strategies. Leading PhRMA member companies are collaborating with relevant U.S. and global public health authorities, including the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC) and World Health Organization (WHO), as well as public health authorities in China and Europe, to understand how pandemic preparedness platforms can be tailored to address the current emergency, and how to accelerate the development of potential treatments.

Members are also sharing the learnings from clinical trials in real time with governments and other companies to advance the development of additional therapies

3. ADVANCING PAST LEARNINGS

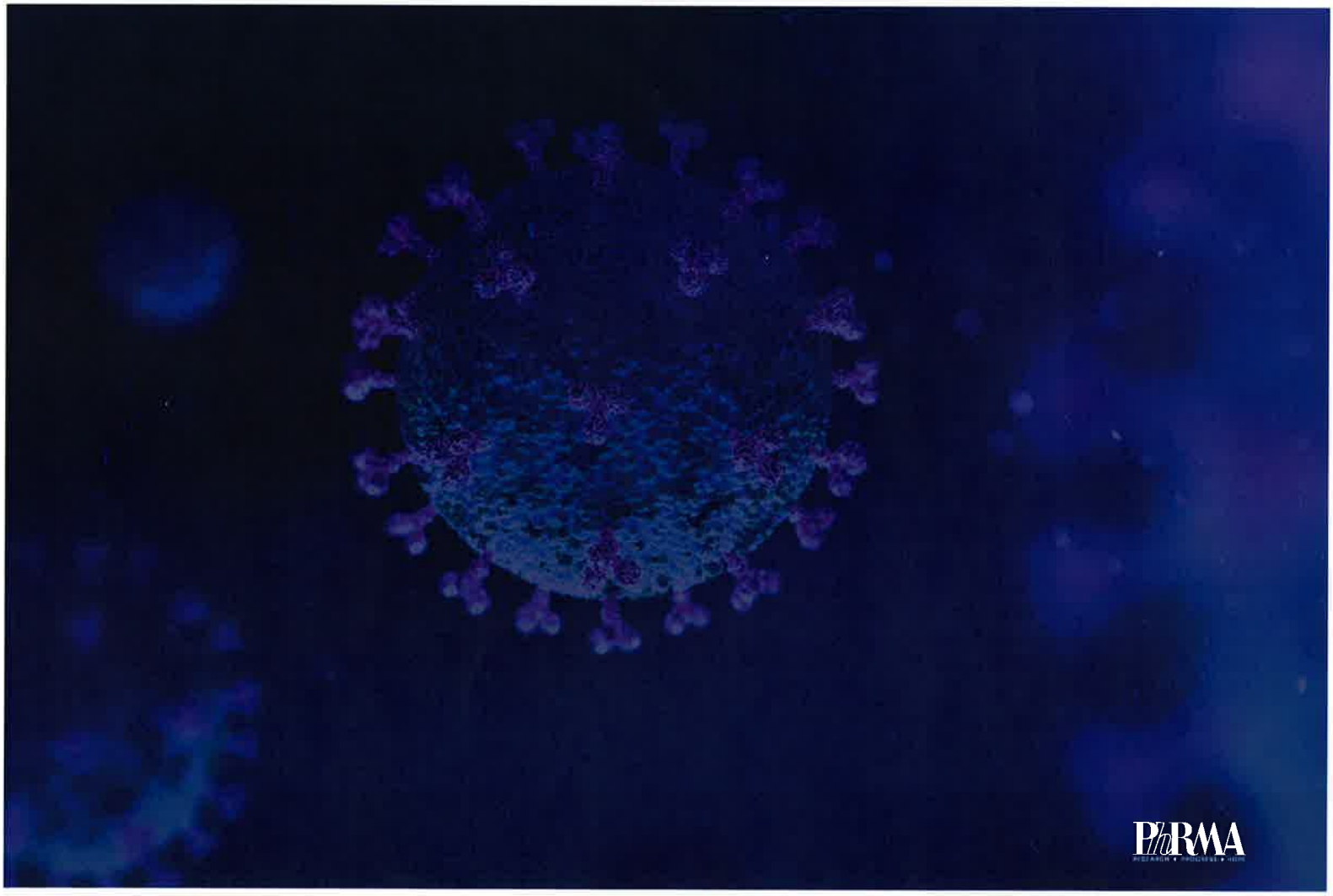
Up until the outbreak began, COVID-19 did not exist. The rapid pace at which researchers have been able to understand this strain and get medicines into human clinical trials is a testament to the lessons learned from past public health emergencies. Furthermore, the biopharmaceutical industry has the unparalleled advantage of decades of scientific research cultivated from experiences with similar viruses, such as MERS, SARS and influenza. These previous public health emergencies have helped put the infrastructure and partnerships in place to enable a more rapid response to emerging threats.

4. MANUFACTURING PRODUCTION

Innovative biopharmaceutical companies have the capacity to manufacture and broadly disseminate vaccines and treatments to patients worldwide. America's biopharmaceutical companies are already ramping up production capacity in anticipation of the discovery of an effective treatment or vaccine. They are also protecting the integrity of the pharmaceutical supply chain and keeping plants open to maintain a steady supply of medicines for patients. All the while, our member companies are staying in constant communication with the U.S. Food and Drug Administration and other regulatory agencies around the world.

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

Read more about the industry's contributions to the COVID-19 pandemic and our principles **here**.



Five Things You Need to Know About the Biopharmaceutical Research Ecosystem During COVID-19

America's biopharmaceutical companies are at the heart of a robust research and development (R&D) ecosystem that develops more innovative medicines than any other country in the world.

Some critics have claimed that this success is because the National Institutes of Health (NIH) use public funds to discover new therapies which are then just handed off to biopharmaceutical companies to be manufactured, packaged and monetized. This fundamental misunderstanding of the way drug development works has led to policy proposals that could seriously harm the U.S. research ecosystem and jeopardize its longstanding success.

Now more than ever, it is critical that both public and private assets can be brought to bear in addressing critical diseases such as COVID-19.

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July 2020

Basic science research is conducted by both the public and private sectors and lays the foundation for our understanding about how the human body functions.

The goal of basic science research is to understand the function of newly discovered molecular compounds and cells, strange phenomena in the body or little-understood disease processes. Many times this new kernel of scientific understanding requires additional research contributions from other scientists to determine whether that new scientific knowledge will inform the development of new research methods, technology platforms or treatments years or decades later. Academic, government and private industry researchers and scientists all contribute to the vast body of basic science research, and that knowledge is shared and expanded upon by scientists through peer-reviewed publications, scientific meetings, filing of patents and licensing of intellectual property (IP).

Because the NIH conducts limited research specifically related to drug development, without the investment of the biopharmaceutical industry the knowledge resulting from basic science research supported by NIH would generate many ideas for potential drugs and drug targets – but very few new medicines.

The biopharmaceutical industry's unique role in the research ecosystem is to utilize its scientific and industrial expertise to take the necessary risks to build upon and further advance basic science research into safe and effective treatments that can be made available to patients. The federal government cannot research, develop and manufacture vaccines and other new treatments without the resources, scientific expertise, R&D, manufacturing and technological platforms from private sector biopharmaceutical companies.

"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."[i]

— **DR. ANTHONY FAUCI** of National Institute of Allergy and Infectious Disease

Much of the success of the U.S. research ecosystem is due to the positive impact of the Bayh-Dole Act on public-private research collaboration.

Congress passed the Bayh-Dole Act in 1980 with bipartisan support to incentivize the private sector to make the substantial and risky investments needed to transform discoveries from government-funded basic research into useful products. Bayh-Dole has helped lay the foundation for the robust and entrepreneurial U.S. R&D ecosystem. Prior to enactment of the Bayh-Dole Act, the government retained the patents on federally-sponsored inventions – and only 5% of those patents were ever used in the private sector.[ii] The reason the U.S. is the global leader of biopharmaceutical innovation is because the IP system promotes competition by ensuring each player excels at their role and is incentivized to take risks and share information throughout the process. Strategic public-private partnerships help support collaboration among governments, scientific institutions and biopharmaceutical, medical device, diagnostics companies and many others to stimulate progress in research and science to develop effective vaccines as well as diagnostics and treatment options critical to address COVID-19.

"We are the place that supports the scientific innovations that lead to these breakthroughs, and ultimately, to new therapies," Collins said in an interview. "But we need to be part of an ecosystem that includes the private sector and philanthropy and advocates for that in order for that to come true."

— DR. FRANCIS COLLINS, Director of the National Institutes of Health and Infectious Disease

https://news.bloomberglaw.com/pharma-and-life-sciences/research-not-heavy-hand-to-tamp-down-drug-costs-nihs-collins

It is not solely a question of dollars invested. NIH has a critical public health mission to uncover new knowledge that will lead to better health for everyone – and we should keep it that way.

Imagine the loss for the advancement of public health if the NIH was solely focused on developing new therapeutics. Through the research grants NIH provides, they not only advance basic science research but also have a critical role to play in training future scientists, developing and supporting medical libraries, training medical librarians and other health information specialists and educating on the importance of prevention for maintaining good health.[iii] NIH-funded studies are critical for increasing our understanding of the natural history of diseases, identifying critical biomarkers and establishing clinical guidelines for best standard of care. Private sector companies regularly collaborate with NIH by providing funding and drug supplies, contracting with clinical trial networks to run industry-sponsored clinical trials and providing scientific expertise to those networks through advisory committees. However, similar to the way NIH cannot fulfill all of the responsibilities of the industry, the industry cannot fulfill all of NIH's responsibilities. Each member of the biopharmaceutical ecosystem plays a unique and vital role.

In cases where public funding is provided, for example, to support clinical research or increase manufacturing capacity for potential new treatments and vaccines for COVID-19, some have called for the government to determine the price if the candidates are successful. This fails to recognize that reducing the incentives for the private sector to invest and take risks could have serious unintended consequences for future innovation.

In the face of the COVID-19 crisis, PhRMA member companies have committed to collaborating with a wide range of partners including working with various governments to ensure that when new treatments and vaccines are approved, they will be available and affordable for patients.[iv] Concerns that the biopharmaceutical industry will inappropriately price future vaccines or treatments are unfounded. During public health emergencies such as pandemics, the biopharmaceutical industry has a track record of responsible pricing and actively partnering with the government to ensure availability and affordability. Dr. Anthony Fauci has said he is not aware of any situation where companies priced vaccines out of reach in pandemic situations.[v]

Further, the Coronavirus Aid, Relief, and Economic Security (CARES) Act requires that products purchased by the federal government, such as vaccines and therapeutics developed using federal funds, will be acquired at a fair and reasonable price.[vi] As Speaker Pelosi described the provision, "The legislation protects against price-gouging of these medicines developed with taxpayer dollars by ensuring that the federal government will only pay a fair and reasonable price for coronavirus vaccines and drugs and providing HHS the authority to ensure that they are affordable in the commercial market."[vii] Any new additional policies that would set prices in the commercial market or make it less attractive to collaborate with the federal government would not only fundamentally set back the industry's ability to respond in a timely way to COVID-19 but would also deter companies from making long-standing investments needed to be able to respond quickly in times of future global health emergencies.

Rather than harming the highly successful U.S. biopharmaceutical research ecosystem and the patients who need innovative treatments, we should look to policies that will support patient access and affordability without undermining the development of tomorrow's life-saving medicines. ***Through thoughtful, market-based approaches we can continue to support a thriving biomedical research ecosystem and allow the biopharmaceutical sector to continue to partner with the public sector to deliver innovative medicines and improve the lives of patients in unprecedented ways.***

[i] Lerman D & A Siddons. "Vaccine prices a flashpoint in coronavirus funding talks," *Roll Call*. February 27, 2020. Available at: https://www.rollcall.com/2020/02/27/vaccine-prices-a-flashpoint-in-coronavirus-funding-talks/

[ii] Government Accountability Office (GAO). (2009). Information on the Government's Right to Assert Ownership Control Over Federally Funded Inventions Available at: www.gao.gov/products/GAO-09-742.

[iii] https://www.nih.gov/about-nih/what-we-do/mission-goals

[iv] https://phrma.org/coronavirus

[v] Lerman D & A Siddons. "Vaccine prices a flashpoint in coronavirus funding talks," *Roll Call*. February 27, 2020. Available at: https://www.rollcall.com/2020/02/27/vaccine-prices-a-flashpoint-in-coronavirus-funding-talks/

[vi] Coronavirus Aid, Relief, and Economic Security (CARES) Act. Available at: https://www.congress.gov/bill/116th-congress/house-bill/748

[vii] " Pelosi Statement on Coronavirus Emergency Response Bill," March 4, 2020. Available at: https://www.speaker.gov/newsroom/3420

WORKING TOGETHER TO FIGHT COVID-19

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Armed with experience garnered from previous outbreaks and a vast storehouse of knowledge about infectious diseases like influenza, malaria and HIV, researchers are working to develop and deliver diagnostics, treatments and vaccines to save lives and restore the rhythms of daily life for billions of people.

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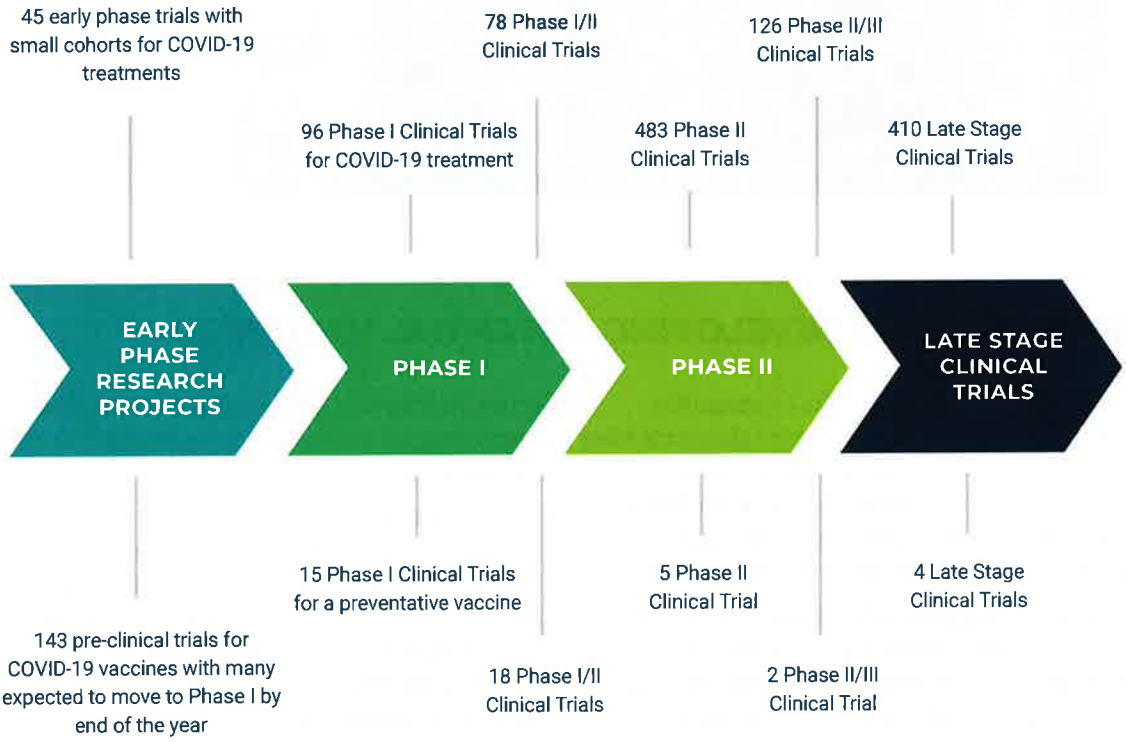
Learn more at PhRMA.org/Coronavirus

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 August 7, 2020, there are **more than 1,500 clinical trials testing COVID-19 treatments and vaccines.**[i] Sponsors are trying a variety of approaches, including 1,432 clinical trials for COVID-19 treatments and 78 clinical trials testing a vaccine, with over 325 of these clinical trials taking place in the United States. Some of the trials are being conducted in multiple countries simultaneously.



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

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 **473 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 1,510 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 1,510 active clinical trials, more than 930 trials are testing medicines previously approved for another indication, such as antiviral combinations, and nearly 200 trials are testing novel compounds.[iii]

COVID-19 Treatments in Development by Phase
(as of August 7, 2020)

Early Clinical Research	Phase I	Phase I/II	Phase II	Phase II/III	Late Stage Clinical Trials
24	44	37	177	57	121

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 26 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.

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

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.

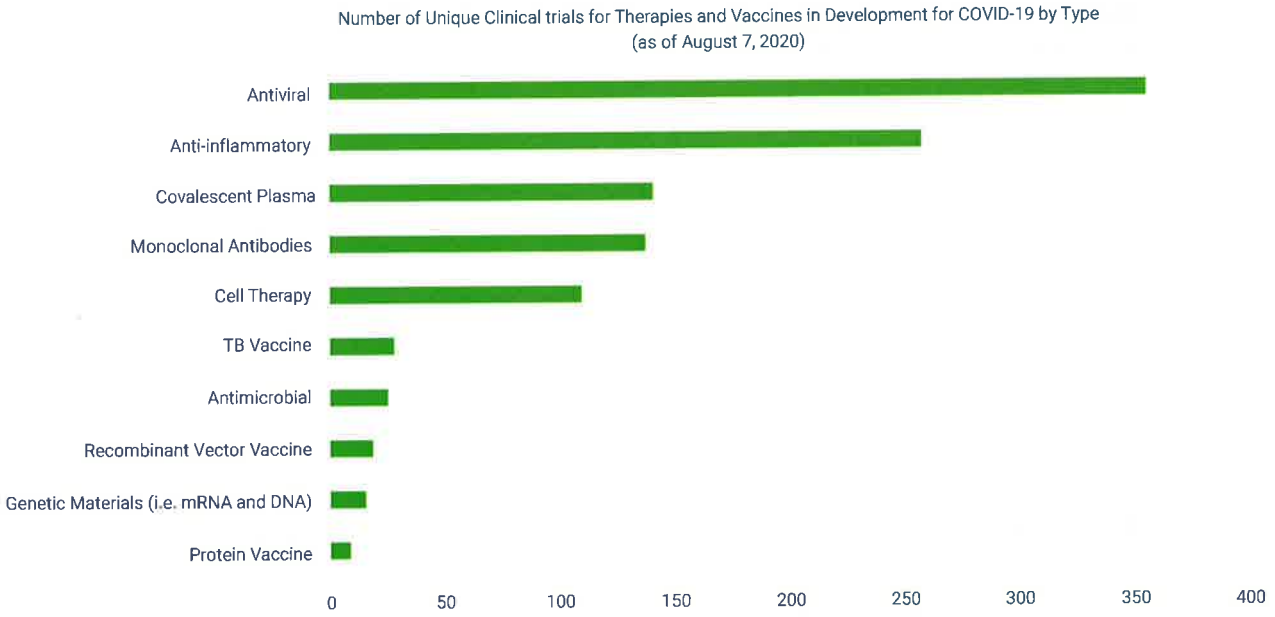
There are currently 78 clinical trials underway to test **26 vaccine candidates.** There are more than 40 trials in phase I, phase II and phase III that are collectively enrolling over 100,000 patients. There are also Phase 3 trials testing a previously approved vaccine, mostly in front-line workers, which are aiming to enroll another 330,000 patients. Additionally, there are 143 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



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 vaccines[v] 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.

[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 August 7, 2020
[ii]Treatments in development by phase as of August 7, 2020. 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-remdesivir
[iv]Clinical trial data as of August 7, 2020
[v]https://innovation.org/diseases/infectious/coronavirus/how-scientists-plan-to-develop-coronavirus-vaccine