The Biopharmaceutical Industry's Efforts to Beat Coronavirus



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Our Commitment to Beat Coronavirus

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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



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.

Supporting Diagnostic Efforts and Developing Treatments and Vaccines

Working Closely with FDA to Support Diagnostic and Serological Testing



YAY

FDA has issued **120** emergency use authorizations for COVID-19 diagnostic tests **196 serological tests to evaluate antibodies** to SARS-CoV-2 are being offered in the United States

6

Data as of 6/19/2020

Developing Treatments and Vaccines to Fight COVID-19

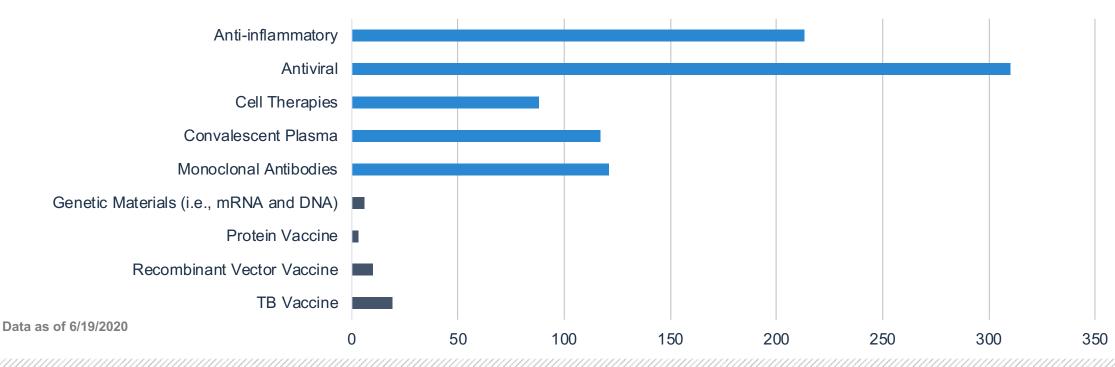
There are **1228 clinical trials under way across the globe** for vaccinations and treatments.



Building a Diverse Research and Development Pipeline

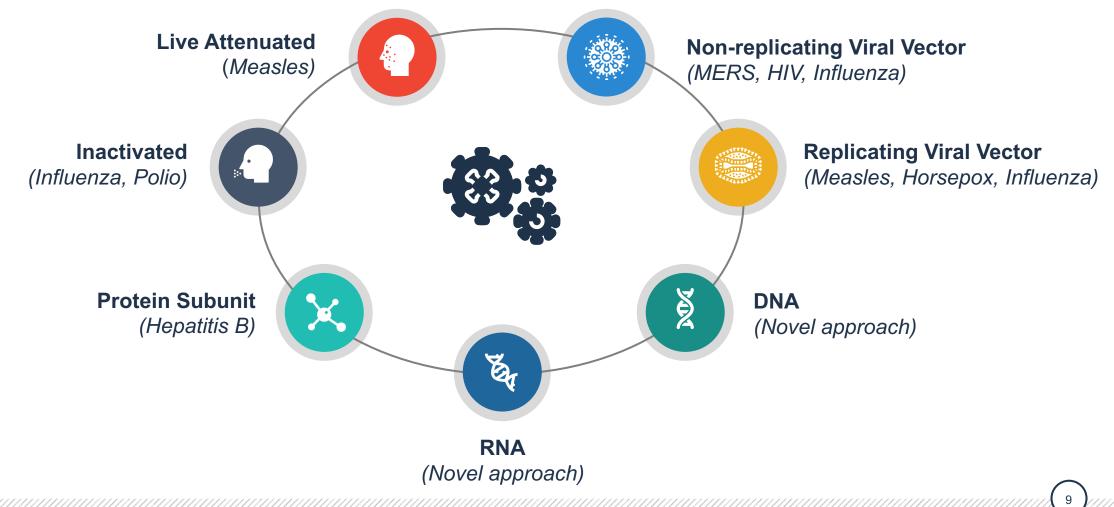
These hundreds of clinical trials represent **multiple approaches for COVID-19 vaccines and therapies.**

Number of Trials Testing Types of Therapies and Vaccines for COVID-19



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

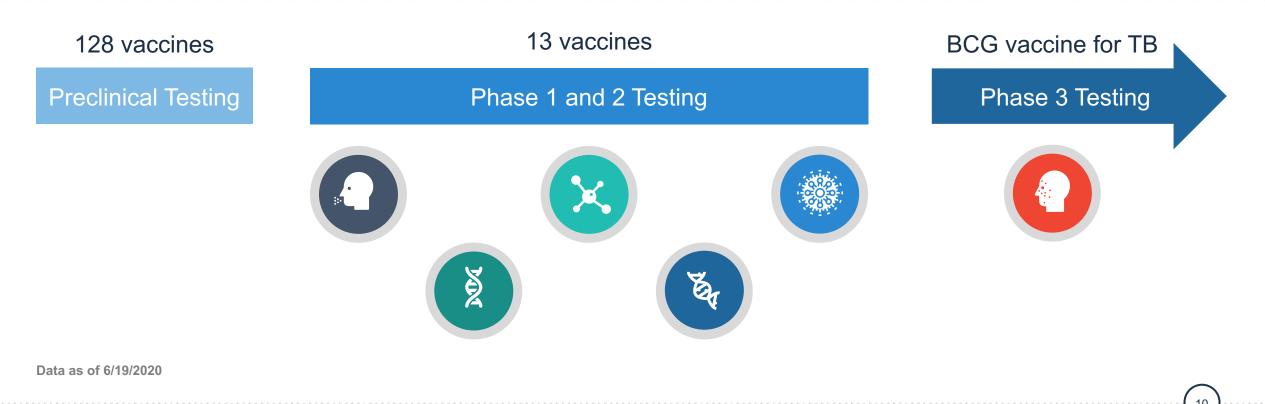
Using Many Approaches to Develop Vaccines



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

Developing and Testing Vaccines to Prevent COVID-19

COVID-19 vaccines currently under investigation include over 140 unique "shots on goal"



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

Faster Timeline

Differing Approaches

Failure Rate

- 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

- 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

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

Developing and Testing Therapies to Treat COVID-19

There are **1188 clinical trials across the globe to test 395 therapies** to treat COVID-19

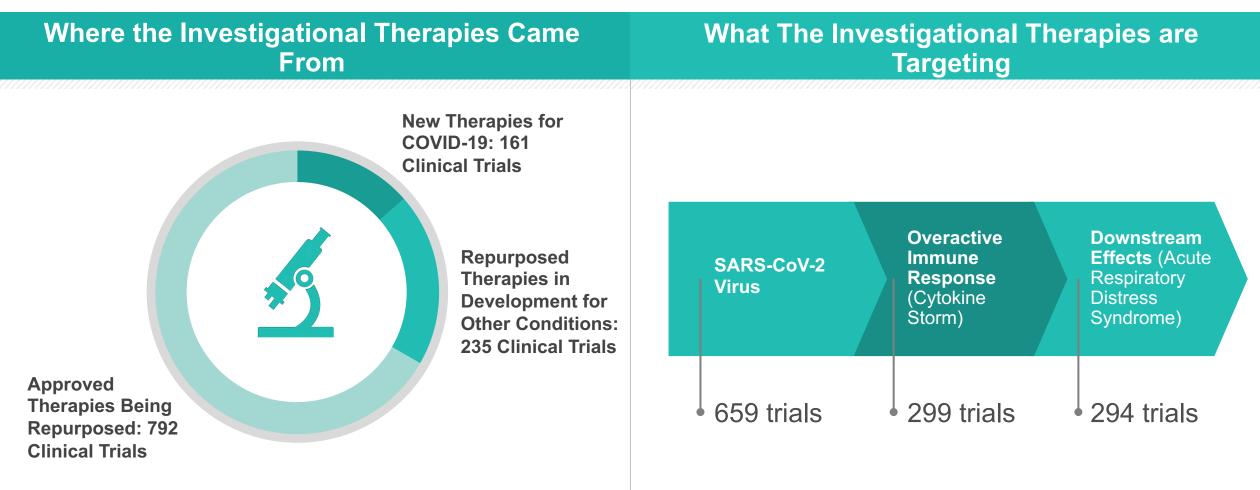
Antiviral 51 Anti-inflammatory 86 Monoclonal antibody 52 Cell Therapy 27 Vasodilator 20 Immunostimulant 33 Antimicrobial 25 Anticoagulant 21 Other 80 Data as of 6/19/2020

Number Of Unique Therapies Under Investigation

12

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

Investigational Therapies to Treat COVID-19



Where to Go for More Information



For More Resources and Information, Visit phrma-jp.org/Coronavirus (Japan) | phrma.org/Coronavirus (US)

