

The Process of Developing and Approving Vaccines

Center Forward Basics
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Overview

As COVID-19, the novel coronavirus, continues to spread, scientists and manufacturers are focusing on developing a vaccine. In January, the coronavirus originated in a seafood and poultry market in Wuhan, China and has since spread to at least 71 countries. Worldwide, more than 173,800 people in 140 countries have been infected and more than 7,281 deaths have been linked to the virus as of March 16, 2020. Scientists believe that the virus is readily transmitted from person to person, but it is currently unclear how far the virus will spread before a vaccine is developed.

Developing a Vaccine

The U.S. Food and Drug Administration (FDA) ensures the safety, effectiveness, and the availability of vaccines for the United States. Before the FDA licenses a vaccine, the vaccine goes through a rigorous testing process while scientists and medical professionals carefully evaluate and determine its safety and effectiveness. Vaccine development begins in the laboratory with extensive research and multiple tests. If the laboratory tests are successful, the vaccine is typically tested in animals. If a vaccine is safe in animals and studies show that it will be safe in people, the vaccine development process continues with clinical trials. There are generally three phases of clinical trials in order to ensure the safety of the volunteers. In Phase 1 of the clinical trials, scientists study how the size of the dose may relate to the side effects and how effective the vaccine may be. If the vaccine is successful in Phase 1 with no side effects, it continues to Phase 2. Phase 2 involves several hundred volunteers and focuses on common short-term side effects and how the size of the dose relates to one's immune response. In Phase 3, typically hundreds of thousands of volunteers participate. In this series, vaccinated people are compared with people who have received a placebo or another vaccine so researchers can learn more about the safety, effectiveness, and common side effects of the vaccine. The FDA strictly monitors the clinical trials in order to assess the safety and effectiveness of each vaccine. Additionally, FDA scientists and medical professionals evaluate the vaccine's physical, chemical, and biological properties and how it is manufactured to ensure it will be consistently made the same way. After the vaccines are licensed, the FDA closely monitors the people who receive the vaccine in order to watch for adverse side effects.

Center Forward Basics

Center Forward brings together members of Congress, not-for profits, academic experts, trade associations, corporations and unions to find common ground. Our mission: to give centrist allies the information they need to craft common sense solutions, and provide those allies the support they need to turn those ideas into results.

In order to meet our challenges we need to put aside the partisan bickering that has gridlocked Washington and come together to find common sense solutions.

For more information, please visit www.center-forward.org

Key Facts

- General Stages of the Development Cycle of a Vaccine:
 - Exploratory Stage
 - o Pre-clinical Stage
 - Clinical Development
 - This is a three-phase process
 - Regulatory review and approval
 - Manufacturing
 - Quality control

Conclusion

On March 11th, 2020, the World Health Organization (WHO) announced that COVID-19 is now officially a pandemic. As the virus continues to spread across the globe, scientists and companies are rushing to develop a safe and effective vaccine. But developing a new commercial vaccine can take over ten years and cost more than \$2 billion. Currently, scientists are working with manufacturers to speed up the vaccine development process, but even with an expedited process it could take up to a

year and a half for a vaccine to be approved for human use.

The Centers for Disease Control and Prevention has recommended a variety of different personal protective measures to prevent the spread of the pandemic. Some of the measures range from improved hand hygiene, frequently cleaning touched surfaces, to school, restaurant, and gym closures and home isolation of ill persons. Additionally, the House of Representatives passed a \$8.3 billion emergency spending bill to combat the spread of the virus by rushing money and supplies to states, hospitals and labs, as well as to key federal agencies searching for vaccines, treatments and shorter term solutions to minimize the spread. Lawmakers are also expected to pass an economic stimulus bill that includes mandated paid leave, strengthened unemployment insurance, emergency nutritional support and fiscal help for states.

Links to Other Resources

- CDC Community Mitigation Guidelines to Prevent Pandemic Influenza United States, 2017
- CDC Ensuring the Safety of Vaccines in the United States
- CDC <u>Vaccine Testing and the Approval Process</u>
- CNN House passes \$8.3 billion total coronavirus response package
- George Washington University <u>Producing Prevention: The Complex Development of Vaccines</u>
- The Hill Congress scrambles to finalize coronavirus funding, surveillance deals
- The Lancet Estimating the cost of vaccine development against epidemic infectious diseases: a cost minimisation study
- The New York Times C.D.C. Officials Warn of Coronavirus Outbreaks in the U.S.
- The New York Times The Coronavirus: What Scientists Have Learned So Far
- The New Yorker How Long will it Take to Develop a Coronavirus Vaccine?