

VACCINE APPROVAL AND OPERATION WARP SPEED

In response to the COVID-19 pandemic, the Trump Administration has expedited the traditional vaccine approval timeline while maintaining safety standards required for all vaccines.

Traditional Vaccine Approval Process

As Figure 1 shows below, the traditional timeline for any pharmaceutical intervention follows a four-step process that takes between 10-15 years from start to finish.¹ These steps include exploratory, preclinical, clinical trials, and Food and Drug Administration (FDA) review and approval phases. The FDA has several mechanisms to expedite the development and review process of drugs and vaccines that address serious conditions.² Four of these mechanisms are being applied where appropriate in response to COVID-19.³

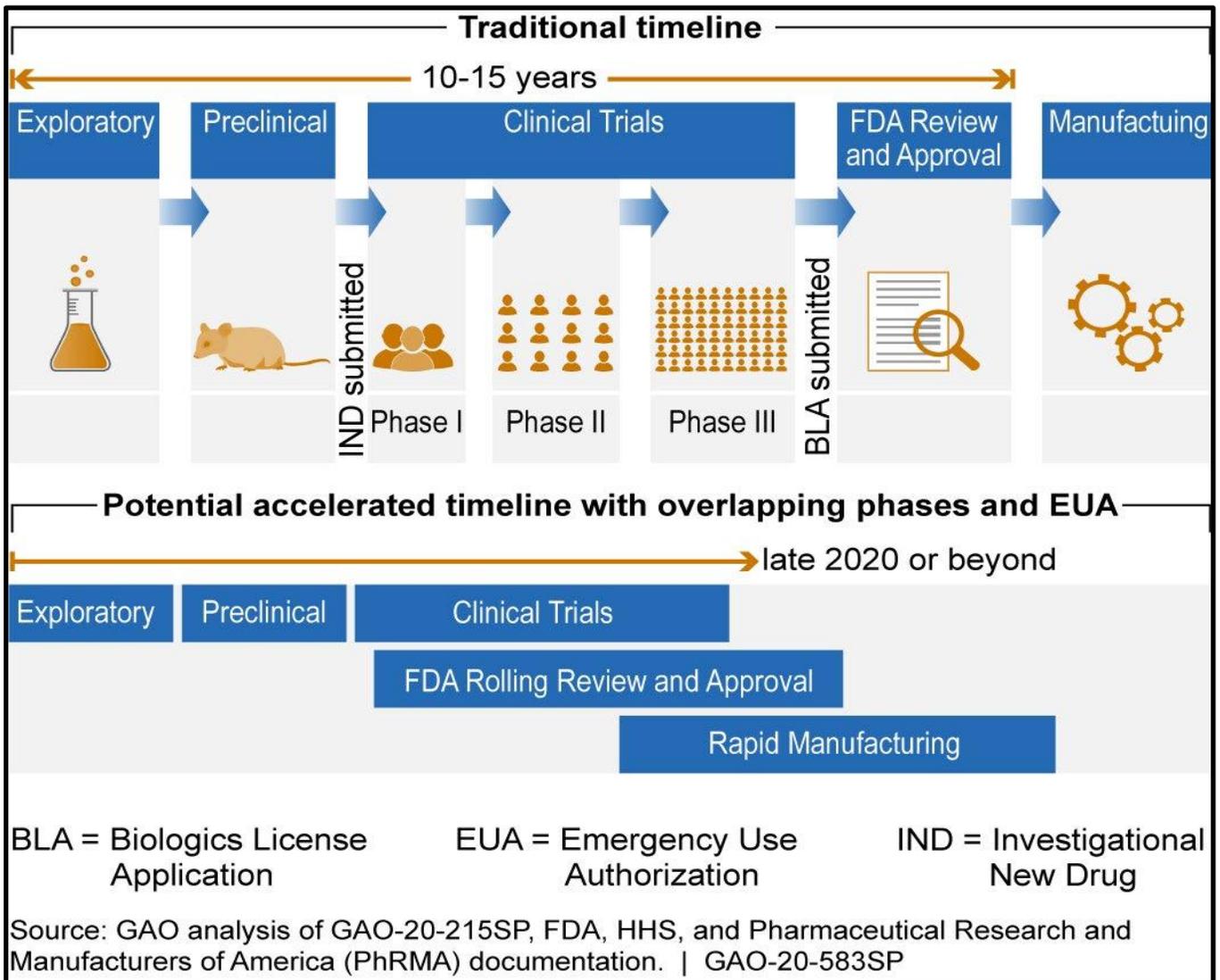
Quick Take

The traditional vaccine approval process can take 10-15 years.

Operation Warp Speed expedites the process with the objective to have a COVID-19 vaccine available by January 2021.

1. **Fast Track Product Designation** – This is intended to streamline the development process for a drug intended to treat a serious condition if an unmet medical need is demonstrated. The sponsor of the vaccine works closely with FDA reviewers throughout the process and can have their applications reviewed in real time.
2. **Breakthrough Designation** - This is similar to *fast track*, but the sponsor also receives intensive FDA guidance, the involvement of senior managers and experienced staff in a proactive, collaborative, cross-disciplinary review to expedite the development and review of a breakthrough therapy; and eligibility for other expedited programs. A drug can qualify if preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies.
3. **Accelerated Approval** - If a drug produces a promising effect on an intermediate measure that indicates that the eventual clinical outcome will likely be favorable, while providing a meaningful advantage over available therapies, the drug can be approved without having to wait for the clinical endpoint.
4. **Priority Review** - If a drug would provide a significant improvement in safety or effectiveness, the FDA then will try to act on the application within six months of filing instead of the standard 10 months.

Figure 1



GAO, May 2020⁴

The FDA can also enable agency access to an Emergency Use Authorization (EUA) to allow access to unapproved medical countermeasures if the Secretary of Health and Human Services (HHS) declares that circumstances exist to justify the emergency use of an unapproved product or unapproved use of a product. The HHS Secretary issued such a declaration on February 4, 2020. Under the declaration the FDA, in consultation with the HHS Office of the Assistant Secretary for Preparedness and Response, the National Institutes of Health (NIH), and Centers for Disease Control and Prevention (CDC) can issue EUAs. However, there are no vaccines currently subject to one.

Operation Warp Speed

On May 15, 2020, the Trump Administration announced the framework for Operation Warp Speed (OWS), “a public-private partnership to facilitate, at an unprecedented pace, the development, manufacturing, and distribution of COVID-19 countermeasures.”⁵ This framework involves cooperation between multiple agencies and departments within HHS,⁶ the Department of Defense (DOD), private firms, and other federal agencies, such as the Departments of Agriculture, Energy, and Veterans Affairs.⁷ The objective of OWS is to have a vaccine available to Americans by January 2021.

Typically, private industry waits until each step in the vaccine development process has been completed to start the next, so as to not take on unnecessary financial risk. For chosen vaccine candidates under OWS, the federal government oversees the testing for safety and efficacy in order to conduct trials simultaneously, when possible.⁸ Through OWS, the federal government is also taking on industry risk by funding the manufacturing and distribution capacity of a few promising candidates before they finish clinical tests.⁹ This ensures that production and distribution is immediate once a safe and effective vaccine is ready and available.

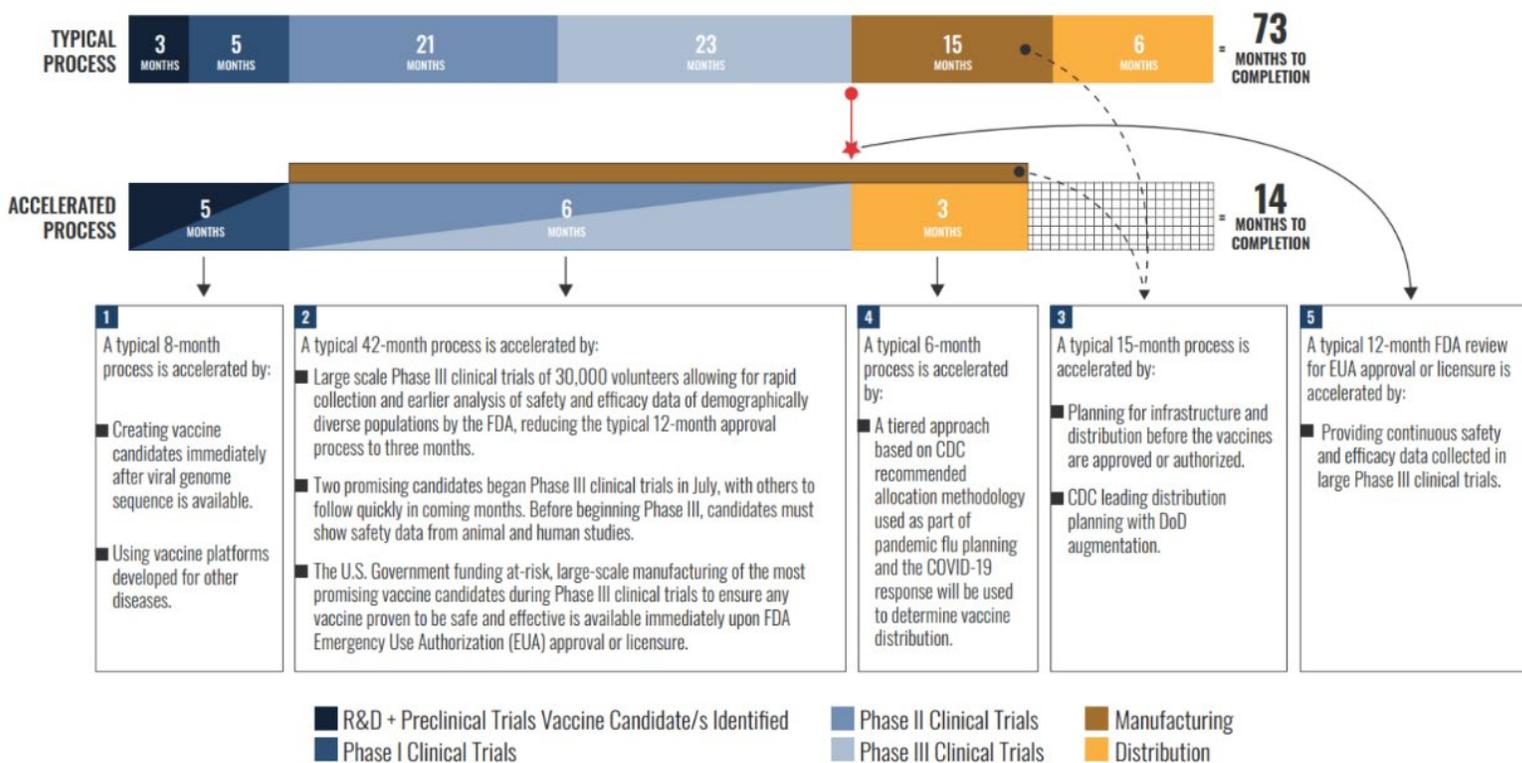
The differences in OWS and the traditional timeline are shown in the chart below.¹⁰

Figure 2



OPERATION WARP SPEED ACCELERATED VACCINE PROCESS

MISSION: Deliver 300 million doses of safe and effective vaccine by 1 January 2021.



Phase 3 clinical trials are currently being done on potential COVID-19 vaccines developed by Moderna, Pfizer-BioNTech, and AstraZeneca with results expected Fall 2020.¹¹ While trials are being completed, HHS and DoD have entered agreements with many companies to manufacture and deliver hundreds of millions of doses of each candidate vaccine, which will be owned by the federal government.¹² This expedites distribution of the vaccine should the clinical trials be successful.

Funding for COVID-19 Vaccine

Though funding has not been appropriated specifically for vaccine development, the CARES Act and the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, appropriated funds that can be used for vaccine development, as detailed below.

- **FDA**— The CARES Act appropriated \$80 million for activities that include the development of necessary medical countermeasures and vaccines. The Coronavirus Preparedness and Response Supplemental Appropriations Act appropriated \$61 million to prevent, prepare for, and respond to coronavirus, domestically or internationally, including the development of necessary medical countermeasures and vaccines.¹³
- **NIH**— The CARES Act appropriated \$945.4 million to prevent, prepare for, and respond to COVID-19, of which not less than \$156 million is provided for vaccine and infectious diseases research facilities. The Coronavirus Preparedness and Response Supplemental Appropriations Act similarly appropriated \$836 million to the National Institute of Allergy and Infectious Diseases.¹⁴
- **Public Health and Social Services Emergency Fund**— The CARES Act appropriated \$27.015 billion for activities that include developing countermeasures and vaccines and purchasing vaccines and therapeutics. The Coronavirus Preparedness and Response Supplemental Appropriations Act appropriated a total of \$3.4 billion to this fund to prevent, prepare for, and respond to COVID-19, domestically or internationally, including the development of necessary medical countermeasures and vaccines, prioritizing platform-based technologies with U.S.-based manufacturing capabilities, and the purchase of vaccines and therapeutics.¹⁵

Please contact the Republican Policy Committee at RPC@mail.house.gov or (202)225-4921 with any questions.

¹ Government Accountability Office (GAO), "The Reward and Risk of Expediting COVID-19 Testing and Vaccine Development," May 28, 2020, <https://blog.gao.gov/2020/05/28/the-reward-and-risk-of-expediting-covid-19-testing-and-vaccine-development/>.

² Agata Dabrowska, et al., Cong. Research Serv., (CRS), *Development and Regulation of Medical Countermeasures for COVID-19 (Vaccines, Diagnostics, and Treatments): Frequently Asked Questions*, RL46427 (June 25, 2020) at <https://www.crs.gov/Reports/R46427>.

³ U.S. Food and Drug Administration (FDA), *Coronavirus (COVID-19) Update*, June 30, 2020, available at <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-action-help-facilitate-timely-development-safe-effective-covid>.

⁴ Government Accountability Office (GAO), "The Reward and Risk of Expediting COVID-19 Testing and Vaccine Development," May 28, 2020, <https://blog.gao.gov/2020/05/28/the-reward-and-risk-of-expediting-covid-19-testing-and-vaccine-development/>.

⁵ <https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html>.

⁶ Specifically, the CDC, FDA, NIH, and the Biomedical Advanced Research and Development Authority (BARDA).

⁷ Dep't of Health and Human Services (HHS), *Trump Administration Announces Framework for 'Operation Warp Speed'*, May 15, 2020, at <https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html>.

⁸ Additionally, the private sector often only communicates with the FDA and review teams at certain steps in the development and review process if they are not accepted into an expedited program. To remedy this, the FDA issued formal guidance for all parties currently developing that makes clear the FDA's criteria for approval and promotes best practices for gaining that approval.

⁹ <https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html>

¹⁰ Dep't of Defense (DOD), "Operation Warp Speed: Accelerated Vaccine Progress" (last accessed Aug. 12, 2020), at <https://media.defense.gov/2020/Aug/12/2002475961/-1/-1/1/WARP-SPEED-VACCINE-TIMELINE.PDF>

¹¹ <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html> (last accessed Sept. 2, 2020).

¹² HHS, *Fact Sheet: Explaining Operation Warp Speed* (last accessed Aug. 19, 2020), <https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html>

¹³ CARES Act, Pub. L. No. 115-136, div. B, tit. I, 134 Stat. 281, 509 (2020); Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Pub. L. No. 116-123, div. A, tit. I, 134 Stat. 146.

¹⁴ CARES Act, div. B, tit. VIII, 134 Stat. at 555-56; Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, div. A, tit. III, 134 Stat. at 148.

¹⁵ CARES Act, div. B, tit. VIII, 134 Stat. at 560-61; Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, div. A, tit. III, 134 Stat. at 149-50