



# Explaining Operation Warp Speed

## What's the goal?

Operation Warp Speed (OWS) aims to deliver 300 million doses of a safe, effective vaccine for COVID-19 by January 2021, as part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics (collectively known as countermeasures).

## How will the goal be accomplished?

By investing in and coordinating countermeasure development, OWS will allow countermeasures such as a vaccine to be delivered to patients more rapidly while adhering to standards for safety and efficacy.

## Who's working on it?

OWS is a partnership among components of the Department of Health and Human Services (HHS), including the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA), and the Department of Defense (DoD). OWS engages with private firms and other federal agencies, including the Department of Agriculture, the Department of Energy, and the Department of Veterans Affairs. It will coordinate existing HHS-wide efforts, including the NIH's Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership, NIH's Rapid Acceleration of Diagnostics (RADx) initiative, and work by BARDA.

## What's the plan and what's happened so far?

**DEVELOPMENT:** To accelerate development while maintaining standards for safety and efficacy, OWS has been selecting the most promising countermeasure candidates and providing coordinated government support.

Protocols for the demonstration of safety and efficacy are being aligned, which will allow the trials to proceed more quickly, and the protocols for the trials will be overseen by the federal government, as opposed to traditional public-private partnerships, in which pharmaceutical companies decide on their own protocols. Rather than eliminating steps from traditional development timelines, steps will proceed simultaneously, such as starting manufacturing of the vaccine at industrial scale well before the demonstration of vaccine efficacy and safety as happens normally. This increases the financial risk, but not the product risk.

Select actions to support OWS vaccine development so far include:

- March 30: HHS [announced](#) \$456 million in funds for Johnson & Johnson's candidate vaccine, with Phase 1 clinical trials set to begin this summer.
- April 16: HHS [made](#) up to \$483 million in support available for Moderna's candidate vaccine, which began Phase 1 trials on March 16 and received a fast-track designation from FDA.
- May 21: HHS [announced](#) up to \$1.2 billion in support for AstraZeneca's candidate vaccine, developed in conjunction with the University of Oxford. The agreement is to make available at least 300 million doses of the vaccine for the United States, with the first doses delivered as early as October 2020 and Phase 3 clinical studies beginning this summer with approximately 30,000 volunteers in the United States.

[As announced](#) on May 15, the vaccine development plan is as follows, subject to change as work proceeds:

- Fourteen promising candidates have been chosen from the 100+ vaccine candidates currently in development—some of them already in clinical trials with U.S. government support.
- The 14 vaccine candidates are being narrowed down to about seven candidates, representing the most promising candidates from a range of technology options, which will go through further testing in early-stage clinical trials.
- Large-scale randomized trials for the demonstration of safety and efficacy will proceed for the most promising candidates.

**MANUFACTURING:** The federal government is making investments in the necessary manufacturing capacity at its own risk, giving firms confidence that they can invest aggressively in development and allowing faster distribution of an eventual vaccine. Manufacturing capacity for selected candidates will be advanced while they are still in development, rather than scaled up after approval or authorization. Manufacturing capacity developed will be used for whatever vaccine is eventually successful, if possible given the nature of the successful product, regardless of which firms have developed the capacity.

Select actions to support OWS manufacturing efforts so far include:

- The May 21, April 16, and March 30 HHS agreements with AstraZeneca, Moderna, and Johnson & Johnson respectively include investments in manufacturing capabilities.
- June 1: HHS [announced](#) a task order with Emergent BioSolutions to advance domestic manufacturing capabilities and capacity for a potential COVID-19 vaccine as well as therapeutics, worth approximately \$628 million.

**DISTRIBUTION:** Before the countermeasures are approved or authorized, the program will build the necessary plans and infrastructure for distribution.

HHS plans for a tiered approach to vaccine distribution, which will build on allocation methodology developed as part of pandemic flu planning and be adjusted based on experience

during the first wave of the COVID-19 response, data on the virus and its impact on populations and the performance of each vaccine, and the needs of the essential workforce. OWS will expand domestic manufacturing and supplies of specialized materials and resources, such as glass vials, that can be necessary for distribution. DoD's involvement will enable faster distribution and administration than would have otherwise been possible.

Select actions to support OWS distribution efforts include:

- May 12: DoD and HHS [announced](#) a \$138 million contract with ApiJect for more than 100 million prefilled syringes for distribution across the United States by year-end 2020, as well as the development of manufacturing capacity for the ultimate production goal of over 500 million prefilled syringes in 2021.
- June 9: HHS and DoD announced a joint effort to increase domestic manufacturing capacity for vials that may be needed for vaccines and treatments:
  - \$204 million to Corning to expand the domestic manufacturing capacity to produce an additional 164 million Valor Glass vials each year if needed.
  - \$143 million to SiO<sub>2</sub> Materials Science to ramp up capacity to produce the company's glass-coated plastic container, which can be used for drugs and vaccines.

### Who's leading OWS?

HHS Secretary Alex Azar and Defense Secretary Mark Esper oversee OWS, with Dr. Moncef Slaoui designated as chief advisor and General Gustave F. Perna nominated to be chief operating officer. To allow these OWS leaders to focus on operational work, in the near future the program will be announcing separate points of contact, with deep expertise and involvement in the program, for communication with Congress and the public.

### What are you doing to make these products affordable for Americans?

As a commitment to making countermeasures affordable for the American people, and as a condition of receiving support from OWS, companies will provide to the U.S. government an allocation of countermeasures developed.

### How is this being funded?

Congress has directed almost \$10 billion to this effort through supplemental funding, including the CARES Act. Congress has also appropriated other flexible funding. The almost \$10 billion specifically directed includes more than \$6.5 billion designated for countermeasure development through BARDA and \$3 billion for NIH research.