Vaccine Development: Normal Process vs. *Operation Warp Speed*

The vaccine development process follows a standard set of steps to ensure vaccines are safe and effective. For the COVID-19 vaccine under *Operation Warp Speed*, no steps were skipped, but they were accelerated to get a vaccine to market more quickly. These steps include:

Step 1
Obtaining Funding
Normal Process

Pharmaceutical companies that wish to develop a new vaccine need to find a way to pay for the project. Often this involves applying for research grants from HHS and other government agencies. The application process can take years.

Operation Warp Speed

For the COVID-19 vaccine, funding was made available by the federal government — no grant applications were required.

Step 2
Preclinical Trials
Normal Process

Pharmaceutical companies hoping to develop a new vaccine need to find a way to pay for the project. Often, this involves applying for research grants from HHS and other government agencies. The application process can take years.

Operation Warp Speed

Previous research into other coronaviruses gave vaccine developers information they could use to create a safe and effective COVID-19 vaccine, streamlining the preclinical research process.

Step 3
Phase I Clinical Trials
Normal Process

Phase I clinical trials are conducted with only a few dozen human volunteers to assess short-term safety and side effects, such as soreness at the injection site and fever with different vaccine doses.

Step 4
Phase II Clinical Trials
Normal Process

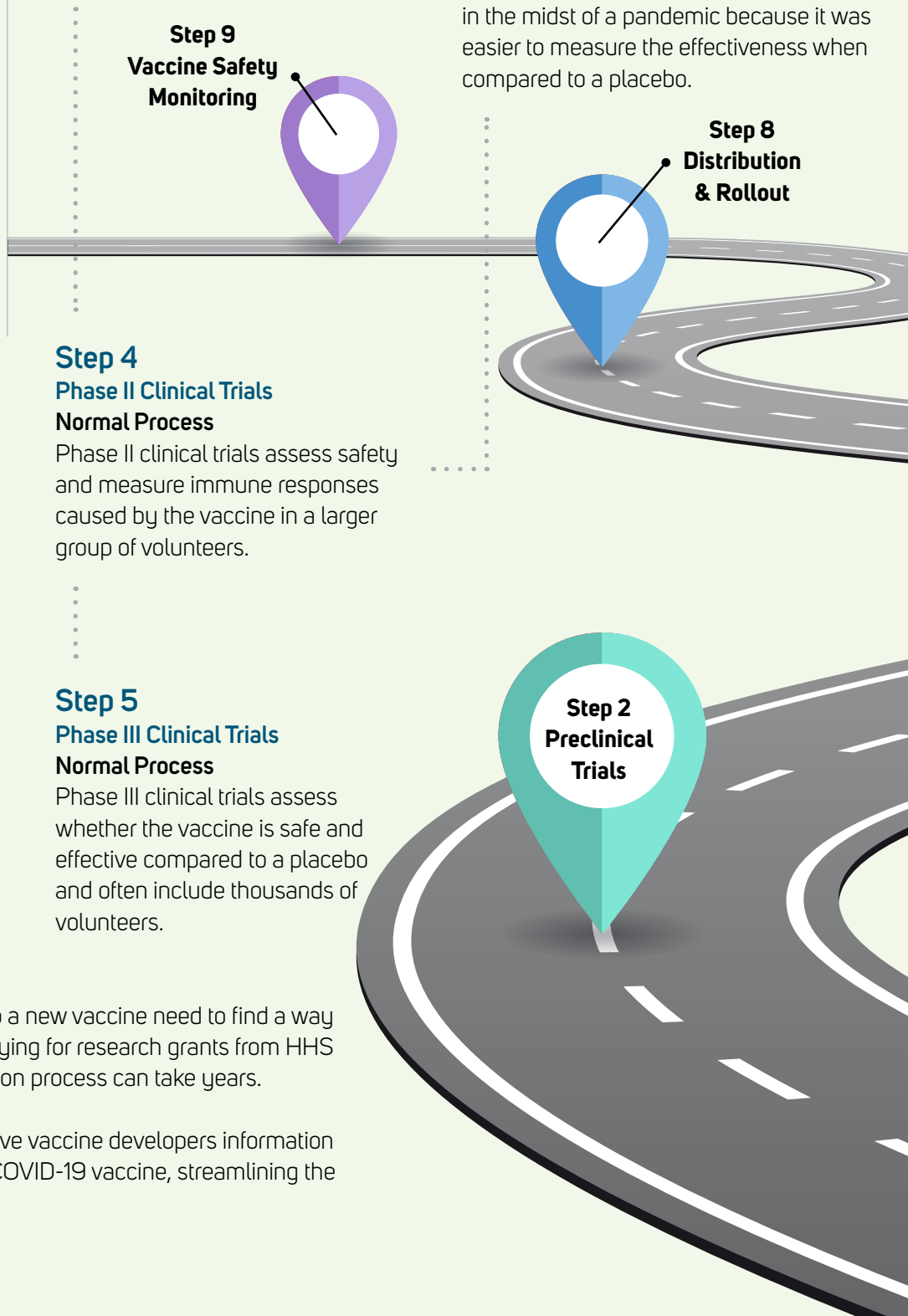
Phase II clinical trials assess safety and measure immune responses caused by the vaccine in a larger group of volunteers.

Step 5
Phase III Clinical Trials
Normal Process

Phase III clinical trials assess whether the vaccine is safe and effective compared to a placebo and often include thousands of volunteers.

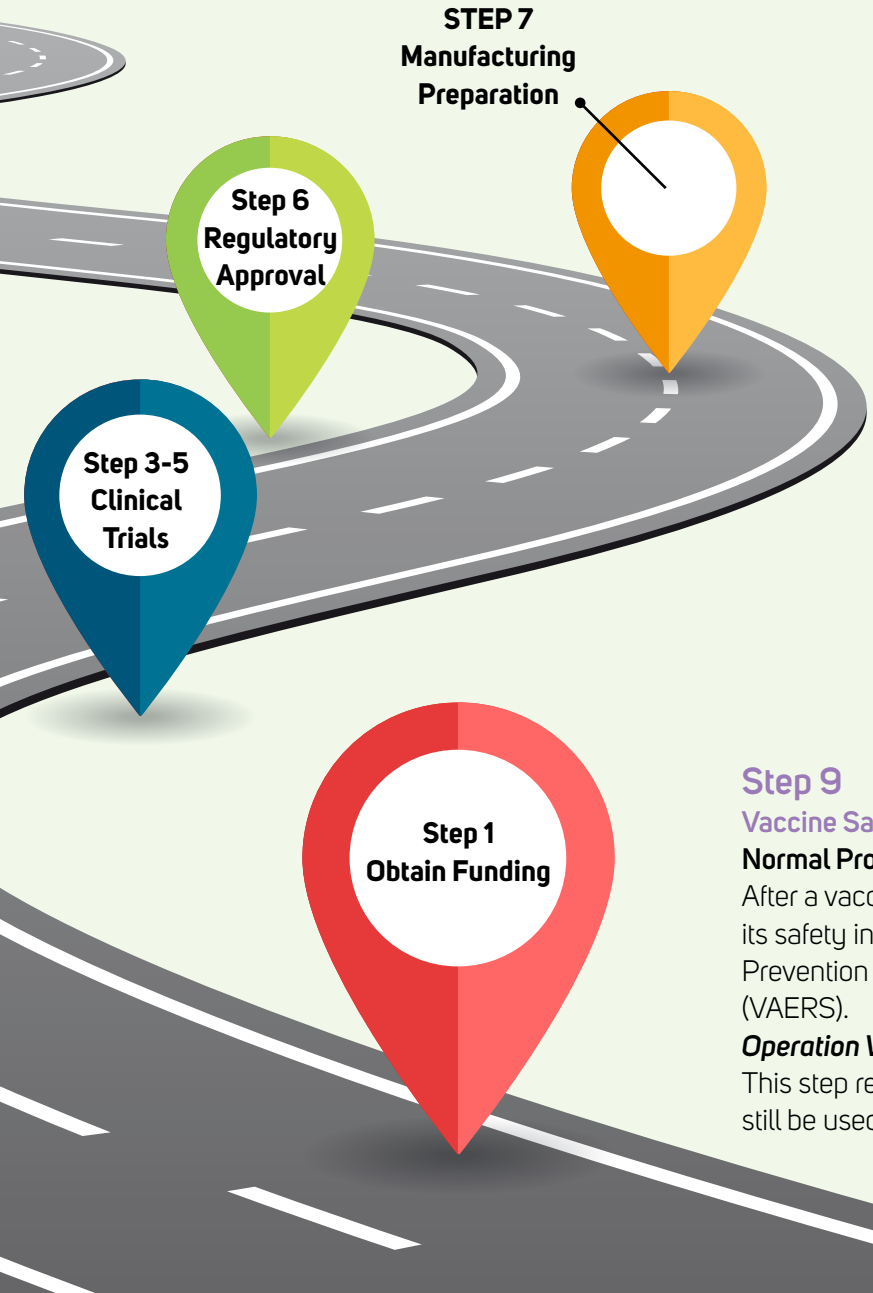
Step 3-5
Phase I, II, and III Clinical Trials
Operation Warp Speed

All steps of the clinical trial process were completed when developing the COVID-19 vaccine. However, some steps were combined — such as Phase I and Phase II, or Phase II and Phase III — to expedite the process. Phase III clinical trials were also completed more quickly in the midst of a pandemic because it was easier to measure the effectiveness when compared to a placebo.



Step 6
Regulatory Approval
Normal Process
After the Phase III clinical trial is complete, the vaccine manufacturer must submit a Biologics License Application providing data on safety, immune responses and effectiveness. The FDA reviews data to determine whether the vaccine should be approved.
Operation Warp Speed
If scientific evidence suggests a vaccine may be safe and effective, the FDA may authorize vaccine use through an Emergency Use Authorization (EUA).

Step 7
Preparing for Manufacturing
Normal Process
After Phase III clinical trials are complete, vaccine manufacturers begin ramping up their ability to produce a large number of vaccine doses. The FDA also conducts periodic inspections of manufacturing facilities.
Operation Warp Speed
The U.S. government and other stakeholders took steps to ramp up manufacturing capacity before the findings from Phase III trials were available. Two vaccine candidates use messenger RNA (mRNA) instead of live or inactive viruses. Vaccines using mRNA are easier to manufacture than live or inactivated vaccines because they do not require handling large quantities of the virus.



Step 8
Distribution and Rollout
Normal Process
After manufacturing capacity is established, vaccine manufacturers make plans to distribute the vaccine to private partners and state health departments, who distribute doses to local health care providers. Part of this step involves ensuring proper shipping and storage methods are used to preserve the vaccine. The FDA also issues guidelines for who should receive the vaccine and how it should be administered.
Operation Warp Speed
The U.S. government created a coalition of experts from the Department of Defense, the Centers for Disease Control and Prevention, and Health and Human Services to work with private partners and state health departments to expedite vaccine distribution, as well as guidelines for its administration. Manufacturers are working closely with distribution partners to ensure vaccines can be stored and transported under proper conditions (particularly the Pfizer BioNTech COVID-19 vaccine which requires ultra-cold storage). The government has also issued a phased rollout plan which prioritizes distribution to vulnerable individuals.

Step 9
Vaccine Safety Monitoring
Normal Process
After a vaccine receives FDA approval, the agency continues to monitor its safety in partnership with the U.S. Centers for Disease Control and Prevention (CDC) through the Vaccine Adverse Event Reporting System (VAERS).
Operation Warp Speed
This step remains the same under *Operation Warp Speed*. VAERS will still be used to track side effects of the COVID-19 vaccine.