



National Indian Health Board
**NATIONAL TRIBAL
COVID-19 RESPONSE**

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12/15/2020

Traditional and COVID Vaccine Development (OWS)
How is a new vaccine developed and approved?

In the United States, the development of new vaccines has six general stages:

1. Experimental stage

This stage is to detect natural or artificial antigens that helps scientists to prevent or treat a disease.

2. Pre-clinical stage

In this stage, scientists try to discover natural or synthetic antigens that produce the same reaction an actual virus or bacteria would cause.

3. Clinical development. In the clinical development stage of vaccine, there are three-phases:

Phase I – The vaccine is given to healthy volunteers to test if it is safe and causes an immune response against the virus.

Phase II – The candidate vaccine is given to people who have characteristics such as, age and physical health like those individuals for whom the new vaccine is planned.

Phase III – The candidate vaccine is given to hundreds or thousands of volunteers and tested for safety and efficacy.

4. Regulatory review and approval

The Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) is responsible for regulating vaccines in the U.S.

5. Manufacturing

FDA continues to supervise vaccine production to ensure continued safety. Periodic facility inspections must continue if the manufacturer holds a license for the vaccine production as part of monitoring of the vaccine and production activities. A manufacturer is required to submit the results of their own tests for potency, safety, and purity for each vaccine lot to the FDA.

6. Quality control

In this phase studies are often performed to determine how long a given vaccine remains protective and to verify the severity of any possible adverse side effects and responses from people who have received the vaccine.

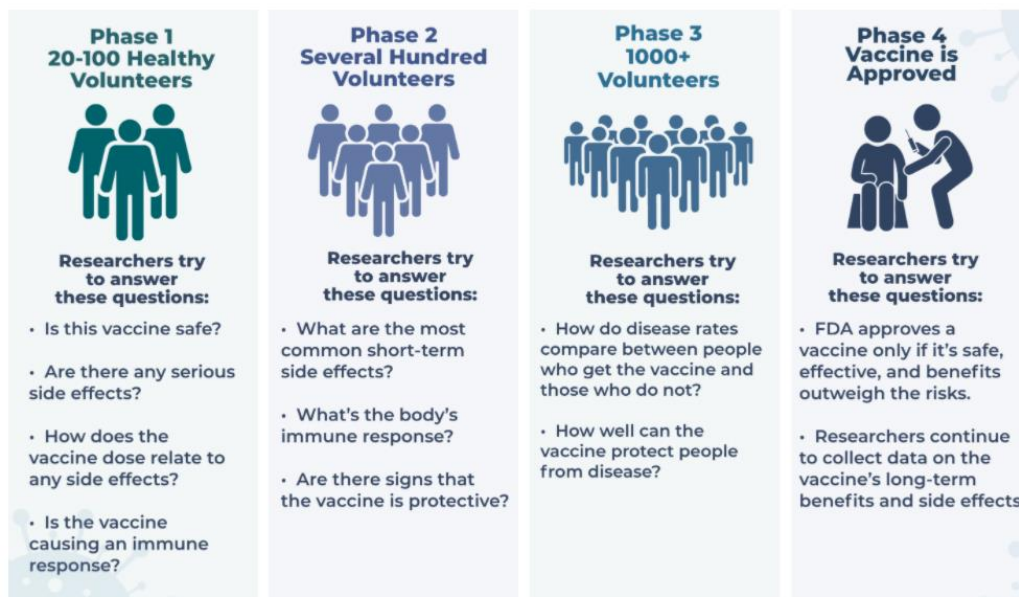


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Clinical Development Stages of Traditional Vaccine Progress



Source: <https://covid19community.nih.gov/resources/understanding-clinical-trials>

Who is the FDA & What Role do they Play in Vaccine Development?

The Food and Drug Administration (FDA) is an agency within the U.S. Department of Health and Human Services. It consists of the Office of the Commissioner and four directorates overseeing the core functional areas of the agency: foods and veterinary medicine, global regulatory operations and policy, medical products and tobacco, and operations. Some of the FDA's responsibilities are to ensure that human and veterinary drugs, vaccines, other biological products and medical devices intended for human use are safe and effective; protect the public from electronic product radiation; assure cosmetics and dietary supplements are safe and properly labeled; regulate tobacco products; and protect and advance the public health. The FDA sets rules for the three phases of clinical trials to ensure safety of the volunteers. They have oversight of the safety, effectiveness and quality of vaccines that are used in the United States.



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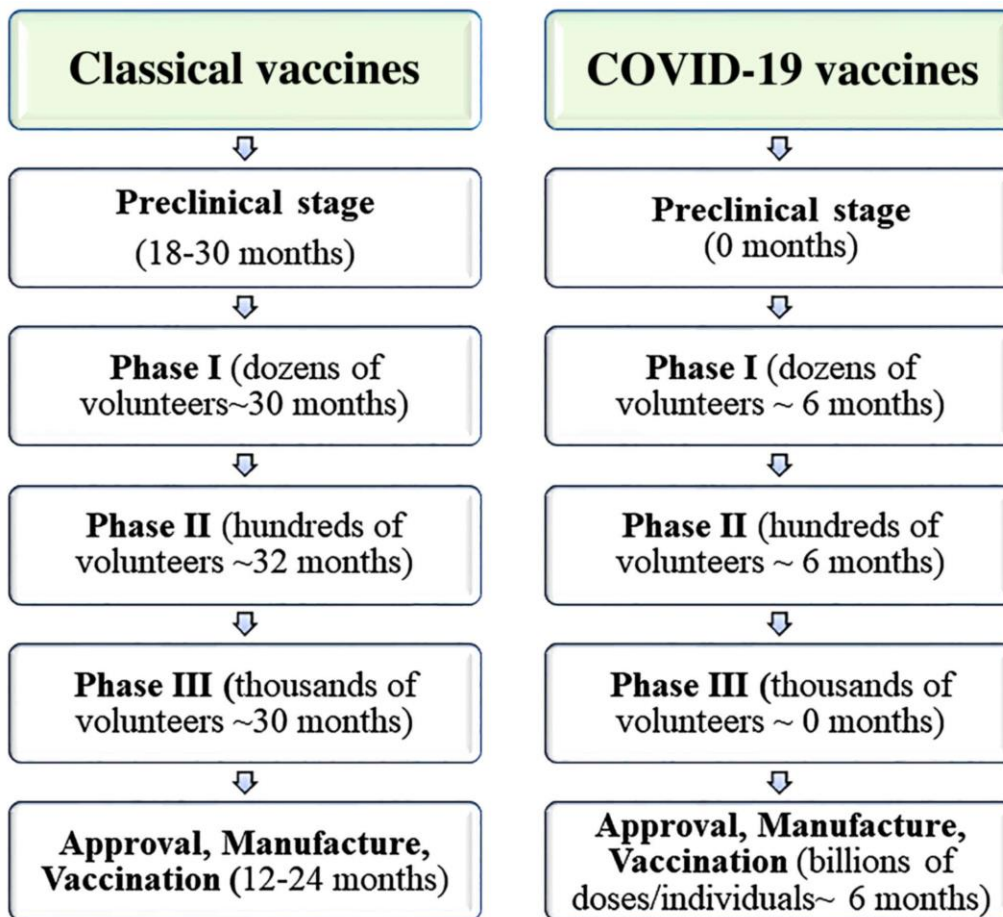
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SARS-CoV-2 (COVID-19) Vaccine Trial

In Operation Warp Speed (OWS), scientists sped up the development, manufacturing, and distribution of COVID-19 vaccines, diagnostics, and therapeutics. The goal is to produce and deliver 300 million doses of effective and safe vaccines in early 2021. How did OWS manage to speed up the process?

1. Known information and experience with previous coronaviruses like severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS).
2. No financial risk to the companies, because of government financing that permit development, trials, manufacturing, and distribution of COVID-19.
3. Simultaneously performed all trial phases (the figure below shows that the Preclinical and Phase I, as well as Phases II and III were conducted at the same time).



Source: <https://www.spandidos-publications.com/10.3892/ijmm.2020.4596>



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Moderna and Pfizer-BioNTech Vaccines

Both Moderna and Pfizer-BioNTech clinical trials started on July 27, 2020. In both studies, each participant received two shots, while some received the real vaccine and others receives a placebo.

The Moderna vaccine is given in two doses, 28 days apart. Moderna estimates that 150-220 American Indians and Alaska Natives (AI/AN) were enrolled in the trial.

The Pfizer-BioNTech shots are given 21 days apart. As of date of this publication, 300 participants of trial enrollees were AI/AN, ages range from 18-85 years. It should be noted that the Navajo Nation participated in the Pfizer-BioNTech COVID-19 vaccine trial on a patient-volunteer basis. The Center for American Indian Health at Johns Hopkins University helped to recruit AI/AN participants for the Pfizer-BioNTech clinical trial.

Moderna
Phase 1: 45 volunteers
Phase 2: 600 volunteers
Phase 3: 30,000 enrolled in the United States

Pfizer-BioNTech
Phase 1: 195 volunteers
Phase 2: More than 11,000 volunteers
Phase 3: More than 43,000 enrolled in the United States, Argentina, Brazil, Germany, South Africa, and Turkey

Protocols for the demonstration of efficacy and safety are being aligned by Operation Warp Speed, which allows the trials to proceed more quickly. The protocols are overseen by the federal government, as opposed to traditional public-private partnerships, in which pharmaceutical companies decide on their own protocols.

Resources

For more information, or to learn more about vaccine trial, explore the following resources:

- NIHB Vaccine Information and Tribal Support Page, <https://www.nihb.org/covid-19/updates/vaccine-information-and-tribal-support-page/>
- FDA, Moderna, Pfizer, and John Hopkins Center for American Indian Health websites:
- CDC: <https://www.cdc.gov/vaccines/basics/test-approve.html>
- Pfizer: www.pfizer.com
- Moderna: <https://www.modernatx.com/modernas-work-potential-vaccine-against-covid-19>
- FDA: <https://www.fda.gov>
- Johns Hopkins University: https://caih.jhu.edu/assets/documents/COVID_vaccine_trials_FAQ_Navajo_revised_2020.1002.pdf

Disclaimer:

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