

JHU Has Stopped Collecting Data As Of

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After three
years of
around-the-
clock tracking
of COVID-19
data from...

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Vaccine Research & Development

HOW CAN COVID-19 VACCINE DEVELOPMENT BE DONE **QUICKLY
AND SAFELY?**



TYPICAL VACCINE DEVELOPMENT TIMELINE

- Each clinical trial phase follows completion of the prior phase
- Can take a long time to accumulate cases to assess vaccine efficacy outside pandemic
- Manufacturing capacity is scaled-up after phase III trial and regulatory approval

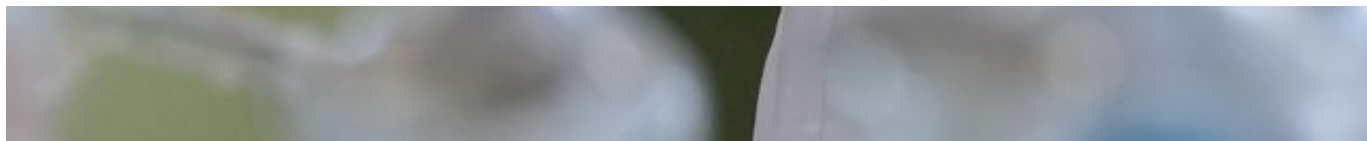


ACCELERATED TIMELINE IN A PANDEMIC

- Some clinical trial phases are combined
- Cases accumulate rapidly to assess vaccine efficacy because of the pandemic
- Manufacturing capacity is scaled up during the clinical trials but at financial risk



SCROLL TO EXPLORE DEVELOPMENT PHASES



TYPICAL TIMELINE

A typical vaccine development timeline takes 5 to 10 years, and sometimes longer, to assess whether the vaccine is safe and efficacious in clinical trials, complete the regulatory approval processes, and manufacture sufficient quantity of vaccine doses for widespread distribution.



ACCELERATED TIMELINE



1-2 YEARS IN TOTAL

COMPARE

to the Accelerated Timeline



**1-10
Years**

Preclinical Trials

Preclinical testing of vaccine candidates typically starts in animal models, first in small mammals such as mice or rats and then non-human primates such as monkeys. Preclinical studies are important for eliminating potential vaccines that are either toxic or do not induce protective immune responses. But many vaccines that appear to be safe and induce protective immune responses in animals fail in human studies. Only vaccine candidates that are very promising in preclinical testing move forward into phase I clinical trials.



Phase I Clinical Trials to Assess Safety, Dosing, and Immune Responses

Phase I clinical trials are the first step in assessing vaccines in people. Typically involving one to several dozen healthy volunteers, phase I trials assess short-term safety (e.g., soreness at the site of injection, fever, muscle aches) and immune responses, often with different vaccine dosages. Only if a vaccine candidate is shown to be safe in phase I trials will it move to larger phase II trials.



ACCELERATED

Phase 1 trials can be completed in two to three months, allowing for two doses of a vaccine three to four weeks apart

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**2-3
Years**

Phase II Clinical Trials to Assess Safety and Immune Responses

Phase II clinical trials continue to assess safety and immune responses but in a larger number and more diverse group of volunteers, typically one to several hundred people. Phase II trials may include target populations of a specific age or sex, or those with underlying medical conditions. Vaccines for children start with adult volunteers and move to progressively younger groups of children. Different types of immune responses are often measured, including antibodies and cell-mediated immunity, but phase II trials do not assess how well a vaccine actually works. Only in phase III trials is vaccine efficacy assessed.



ACCELERATED

Phase 2 trials can be completed in three to four months, allowing for longer follow-up to better assess safety and immunogenicity. This timeline is shortened when phase 1 and phase 2 trials are combined.

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**2-4
Years**

Phase III Clinical Trials to Assess Safety and Efficacy

Phase III clinical trials are critical to understanding whether vaccines are safe and effective. Phase III trials often include tens of thousands of volunteers. Participants are chosen at random to receive the vaccine or a placebo. In Phase III, participants and most of the study investigators do not know who has received the vaccine and who received the placebo. Participants are then followed to see how many in each group get the disease. Assessing short- and long-term safety is also a major goal of phase 3 trials.



ACCELERATED

Phase 3 trials may take six to nine months to allow early assessment of safety and efficacy, particularly if conducted in areas with a high risk of infection, but with follow-up continuing for two years or more to assess long-term safety and efficacy.

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Regulatory Approval Process

Each country has a regulatory approval process for vaccines. In the United States, the Food and Drug Administration (FDA) is responsible for regulating vaccines. In situations when there is good scientific reason to believe that a vaccine is safe and is likely to prevent disease, the FDA may authorize its use through an Emergency Use Authorization (EAU) even if definitive proof of the efficacy of the vaccine is not known, especially for diseases that cause high mortality.



Scaling Up Vaccine Manufacturing

Scaling up vaccine manufacturing is typically done near the end of the regulatory process because of the huge financial investment needed. In the United States, the FDA will inspect the manufacturing facilities. The cost of developing a new vaccine can be several billion U.S. dollars prior to the scale up of manufacturing facilities.



Post-Licensure Vaccine Safety Monitoring

After a vaccine is approved and in widespread use, it is critically important to continue to monitor vaccine safety. Some very rare side effects may only be detectable when large numbers of people have been vaccinated. Safety concerns that are discovered at this late stage could lead a licensed vaccine to be withdrawn from use, although this is very rare.