

The Difference Between FDA Approval and FDA Emergency Use Authorization



Development

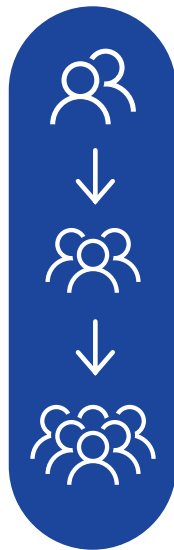
Organizations develop the vaccination to be tested.

FDA Emergency Use Authorization

To expedite vaccines for emergency use, testing and production are done at the same time, followed by approval and distribution.

Production & Testing

Mass amounts of vaccinations are made at the same time as testing is being performed.



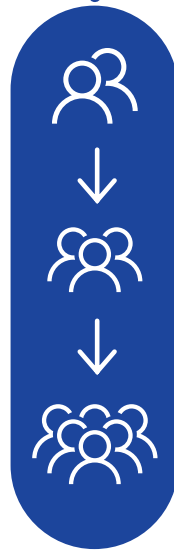
FDA Approval

When time is not so much of the essence, testing is done first, followed by approval, and then production and distribution.

Testing

Three phases of clinical trials are conducted:

- A. Safety & Effectiveness are tested by administering to a small number of healthy people.
- B. A diverse group of hundreds of people with health conditions and differing demographics is tested.
- C. Placebos are tested against vaccines across thousands of diverse individuals.



Approval

Organizations that produce the vaccine apply for Emergency Use Authorization.



Approval

Organizations that produce the vaccine submit a Biologics License Application and if the FDA deems the vaccine safe and effective, the license is granted for the vaccine.



Distribution

The vaccine is made available for use.



Production

Mass amounts of the vaccine are made.



Distribution

The vaccine is made available for use.



In both cases, the same steps are followed, however, in Emergency Use Authorization, vaccines are able to be distributed sooner because they were being produced at the same time as testing.

They are still subject to approval prior to distribution in the same manner as a vaccine going through the FDA Approval process.