THE TOUGH JOURNEY TO YOU: HOW THE COVID-19 VACCINE PROVES ITSELF

AUTHOR: RI XU, PHD
MANAGING EDITOR: KILLIAN KLEFFNER, PHD

Vaccines are the great protectors of our life from death or other severe health risks. Before vaccines come into the market, our only protection is protective wear, distancing, and staying at home.

So, when our best action is to stay at home, how is the vaccine being developed? Vaccines have to complete a difficult journey due to strict regulations. Before regulatory approval, vaccine candidates get filtered out during the regulatory process (Figure 1). Let's say we initially had 500 vaccine candidates, but only 3 end up on the market—497 were rejected.

Why such strict regulations? Regulations guarantee vaccine safety and efficacy; we need to ensure the vaccine does not kill or cause severe damage to human beings. Now let's look at the regulatory process. A vaccine candidate must successfully pass several stages in its development process before being available to the market: discovery, pre-clinical development, clinical trials, and regulatory approval (Figure 1).

- **Discovery phase.** Researchers identify the vaccine candidates (and vaccine ingredients) through massive research and diagnostic tests in the lab.
- **Pre-clinical development.** Animal models are used to confirm the best dosage and delivery (e.g., how many times to inject for efficacy and safety).
- **Clinical trials.** We test the vaccine on humans. From Phase 1 to Phase 3, the number of volunteers being tested increases. If a vaccine candidate shows significant safety concerns or inefficiency, it will not enter the next phase. At the end of Phase 3, sometimes thousands of humans have already tried the vaccine and ensured its safety.

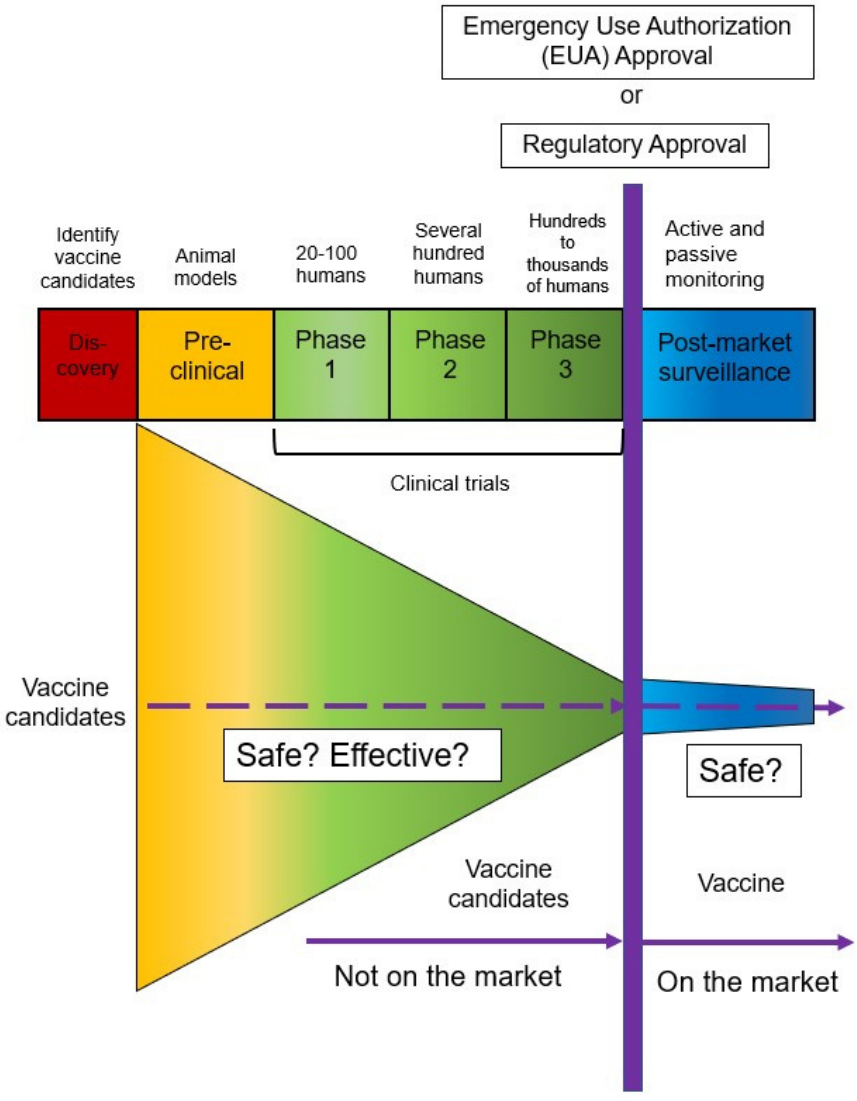

Figure 1 The development and regulatory approval process of the vaccine. Copyright of the author, Ri Xu.

THE TOUGH JOURNEY TO YOU: HOW THE COVID-19 VACCINE PROVES ITSELF

- **Emergency Use Authorization (EUA) approval or regulatory approval.** For regulatory approval, the manufacturer (usually a pharmaceutical company) that developed the vaccine writes and submits documents reporting how the vaccine is effective and safe during its development process. Regulatory authorities (e.g., Food and Drug Agency (FDA)) then review the documents strictly and approve the vaccine for use. However, for emergency purposes, before Phase 3 ends, when the data gathered are adequate to tell the effectiveness and safety of the vaccine, the manufacturer can submit an EUA request to the FDA to gain approval. The EUA submission circumvents the step of waiting for all the data but still guarantees safety and efficacy from the available data.

- **Post-market surveillance.** Even after the vaccines reach the market, we continue to assess them through post-market surveillance to further ensure vaccine safety. The health care centers and monitoring systems actively monitor vaccine safety. Any patients or health care professionals can report adverse events to the vaccine adverse event reporting system (VAERS).

Fortunately, the development processes of COVID-19 vaccines have been the fastest in history, thanks to our increasingly advanced technologies, the seamless collaboration of different health sectors, and the use of EUA approval process.

Therefore, before the vaccine reaches you, it has been through an arduous journey. “Born” in the lab, the vaccine had to prove its efficacy and safety through each development phase, gain regulatory approval, and continue to prove itself under constant surveillance. Now, would you like to give a chance to the vaccine so that it can protect you?

References and Further Reading

1. The journey to your child’s vaccine. (https://www.cdc.gov/vaccines/parents/infographics/journey-of-child-vaccine.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fparents%2Finfographics%2Fjourney-of-child-vaccine-text.html)

2. Emergency Use Authorization for Vaccines Explained (https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained)

3. Working Hard or Hardly Working? Regulatory Bottlenecks in Developing a COVID-19 Vaccine (https://www.sciencedirect.com/science/article/abs/pii/S0167779920301682?casa_token=YF8IB1v2x_MAAAAA:d4vMdNj6fkGJdAF3id5H2T0TUhhGF2aI9SMXa5SCY8ITjOsofvz-q4oXRu4kfBxCYQmz5PgyjBHa)