Ballad Health COVID-19 Vaccine Workgroup Newsletter

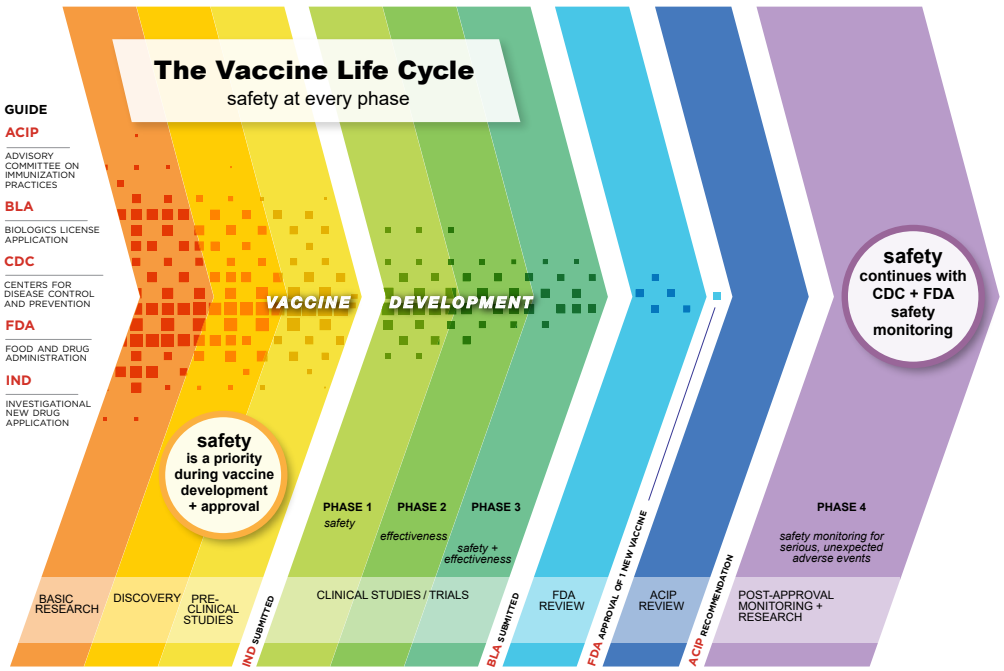
Second Edition – Nov. 17, 2020

In this issue: Vaccine Regulatory Approval – how are vaccines approved by the government?

There are multiple regulatory paths through which a vaccine can be approved by the FDA through the Center for Biologics Evaluation and Research (CBER), which is responsible for regulating vaccines in the United States.

Vaccine clinical development is approved in the same general way as drugs and other biologics. You can read more about this process here.

Full approval	Expanded investigational access	Emergency Use Authorization
• The traditional way we think of new therapies getting approved by the FDA • Drugs are approved through a new drug application (NDA). • Vaccines and biologics are approved through a Biological license application (BLA). • Drugs or biologics can also get accelerated approval, which is still considered full approval but is based on a validated surrogate endpoint. • Ex: protease inhibitors	• Sometimes called "compassionate use" • Used in life threatening conditions for a patient to get access to a therapy outside of a clinical trail • Ex: Convalescent plasma	• Requires a lower standard for use because it's needed quickly in an emergency • EUAs only require FDA to determine a product "may" be effective and that benefits are likely to outweigh risks. • Ex: remdesevir (which then went on to get full approval)



LEARN MORE

FDA VACCINE DEVELOPMENT + APPROVAL PROCESS http://go.usa.gov/xvvNd

CDC VACCINE SAFETY MONITORING + RESEARCH http://go.usa.gov/xvvNe

Reference

How and when will a COVID-19 vaccine get approval?

Currently, the prevailing thought is that the vaccines currently undergoing clinical trials will seek Emergency Use Authorization (EUA). EUA is the fastest way to get a treatment or a vaccine in the hands of people who need it most. However, this path is not without concerns. First, many worry that the EUA standards are too low to ensure public confidence in the vaccine. The FDA has committed to getting at least two months of safety data after all participants in a trial have received their second dose of the vaccine, but some think that monitoring should be extended. If/when a company seeks an EUA from the FDA for a COVID-19 vaccine, the FDA has also committed to seeking feedback from the Vaccines and Related Biologicals Products Advisory Committee (VRBPAC). Second, if a vaccine candidate does achieve EUA, that may make it challenging for other companies to continue to carry on their trials (it's difficult to convince people to sign up for the possibility of receiving a placebo when they know they could go and get the actual vaccine). Pfizer has said in a letter to the FDA that they would have an "ethical obligation" to inform their blinded participants whether they'd received the vaccine or not, which would effectively end the trial and make it impossible to gather further data on the placebo arm.

An alternative to EUA would be for a vaccine manufacturer to ask the FDA for Expanded Access. This type of approval has been used for the meningococcal B vaccine in college students. In this scenario, trials can continue because the public has limited access to the vaccine. You can read more here.

How are the ACIP and CDC involved in the process?

When a vaccine is under investigation, prior to being approved by the FDA, the Advisory Committee on Immunization Practices (ACIP) convenes a working group to examine the evidence related to the vaccine candidate. If the vaccine is approved by the FDA, the ACIP working group then presents its findings to the ACIP to vote on whether and how to recommend the vaccine, including schedule, age group, and dose. ACIP recommendations are forwarded to the CDC director for approval before being included in the CDC vaccine schedule. In the case of the COVID-19 vaccine, the ACIP workgroup has convened several times this year, most recently at the end of October. You can read more about ACIP here.

For additional detail, please see COVID-19 vaccine trackers:

Vizient is a healthcare performance improvement company Vizient vaccine tracker

The Regulatory Affairs Professionals Society (RAPS) https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-vaccine-tracker

The New York Times tracker has won wide endorsement, including from the Hopkins Coronavirus Resource Center COVID-19 Vaccine Tracker