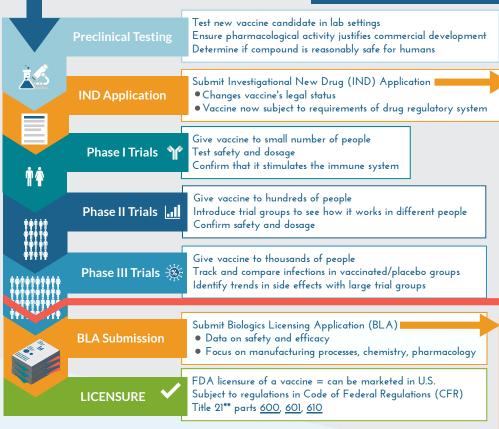
VACCINE TESTING ROADMAP

A Comprehensive Process Driven by Ethics

The Process

Vaccines go through rigorous testing and consideration before they are ever given to humans. The process is overseen by many experts and is governed by ethical principles. FDA licensure/approval = product provides a benefit, which outweighs the potential risk.



Data including:

- Pharmacology & toxicology studies (not in humans)
- Vaccine composition, manufacturer, stability, controls
- Supply of consistent batches

Logistical and Ethical Considerations

- Protocols for planned clinical trials
- Info on investigators who will run clinical trials
- · Commitment to obtaining informed consent
- Commitment to Institutional Review Board (IRB)

Vaccines are regulated under the Federal Food, Drug, and Cosmetic Act

During public health emergencies an Emergency Use Authorization (EUA) application may be filed instead of a BLA, and this may be done before completion of Phase III trials.*

- Drugs follow this exact same process, but approval/licensure standards are slightly different.
- A company seeking approval for a drug would submit a New Drug Application (NDA) instead of BLA.
- Chemical drugs are highly purified and easy to analyze. Biological products like vaccines are not as simple; even small changes in the manufacturing process can affect the final product, so manufacturing controls are extremely important.

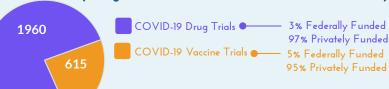
COVID-19 Clinical Trials 藥藥藥

EUA's and Licenses in the U.S.

Licensed vaccine: Pfizer-BioNTech/Comirnaty* Moderna/Spikevax Vaccines with EUAs: <u>Moderna</u> and <u>Janssen</u>* All 3 undergoing continued clinical trials

Any unique vaccine may have multiple active, ongoing clinical trials at once

COVID-19 Drug and Vaccine Trials Currently Registered on clinicaltrials.gov (Being Conducted with At Least 1 Site in the U.S.)



Number of Unique Vaccines in Each Trial Phase Across the Globe

30 10 10

Phase I/II Phase II Phase II/III Phase III New York Times Coronavirus Vaccine Tracker Licensed/ Approved

Abandoned After Trials

** Links to additional CFR 21 Parts of Interest

21CFR Part 312 <u>Investigational New Drug Application</u>

21CFR Part 314 NDA Applications

21CFR Part 50 Protection of Human

21CFR Part 54 Financial Disclosure by Clinical 21CFR Part 56 Institutional Review Boards





www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101

^{*} For more information refer to our Emergency Use Authorizations: A Roadmap Fact Sheet