VACCINE APPROVAL IN THE UNITED STATES

"At the FDA, we uphold globally respected standards for product quality, safety, and efficacy. We monitor the entire process of vaccine development from beginning to end and then follow these products after they are made available to the public."

— Dr. Peter Marks, Food and Drug Administration (FDA)

CVEEP
Champions for
Vaccine Education,
Equity + Progress

COVID-19 vaccine development is following the FDA's gold-standard review process that includes research, multi-stage clinical trials, robust regulatory review and approvals, and ongoing safety monitoring once a vaccine becomes publicly available.

RESEARCH

Lab testing identifies antigens that can prevent disease and assesses the ability and safety of causing an immune response.

If a vaccine candidate progresses past this stage, the sponsor submits an Investigational New Drug application to the FDA. This application describes the proposed clinical trial process.

CLINICAL TRIALS

The vaccine sponsor is required to complete three progressive phases of human testing, starting with validating that the vaccine is safe in healthy people. Later phases test whether the vaccine produces an effective immune response.

Clinical trial protocols are reviewed by regulatory authorities and approved by an Institutional Review Board, which is an independent committee that reviews the methods proposed for research.

Clinical trials are overseen by a group of independent experts called a Data and Safety Monitoring Committee. Trial investigators are also responsible for monitoring participant health, and participants in the trial have regular follow-ups.

REGULATORY REVIEW & APPROVAL

If human clinical trials are successful, the sponsor will submit a biologics license application (BLA) or an Emergency Use Authorization (EUA) to the FDA.

Before FDA grants a license to manufacture the vaccine, FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) will review and evaluate data during a public meeting to make a recommendation on the application status.

After a vaccine is approved by the FDA, the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) develops and distributes recommendations on the *use* of the vaccine.

POST-APPROVAL SAFETY MONITORING

After a vaccine is licensed, CDC continues monitoring for vaccine safety.

Surveillance activities include the Vaccine Adverse Event Reporting System (VAERS), a national system used by scientists at FDA and the CDC to collect reports of adverse events (possible side effects) that happen after vaccination.

Scientists use CDC's Vaccine Safety Datalink (VSD), an ongoing collaboration between CDC and healthcare organizations, to help determine if possible side effects identified using VAERS are related to vaccination.