

FDA VACCINE FACTS

www.fda.gov/vaccines

#FDAVaccineFacts

The Path for Vaccines from Research to FDA Approval

Research and Discovery

Scientists develop concepts for a vaccine based on how the virus or bacteria causes disease in humans. They test their ideas in the laboratory.

Preclinical Research

Before a vaccine is tested in humans, researchers do intensive safety and efficacy studies in the laboratory. Researchers also develop a vaccine manufacturing process to help ensure that research vaccines are sterile, pure, potent, and consistent from lot-to-lot. The FDA receives the results of the preclinical research and manufacturing information in an Investigational New Drug (IND) application.

Clinical Trials

After FDA reviews the IND application, researchers test the safety and effectiveness of the vaccine in volunteers in phase 1, 2, and 3 clinical trials. Each phase depends on the establishment of the safety of the vaccine candidate in the phase before it, involving more volunteers in each subsequent phase. By the time a vaccine reaches phase 3, it's generally given to thousands of people, with those who receive the vaccine compared to those who receive a placebo.

Manufacturing

Vaccine manufacturing is complex. Manufacturers must develop a process to consistently and reliably produce thousands of vaccine doses. Before approval, the FDA works closely with vaccine manufacturers to develop the lot release protocol - a template of the tests that will be conducted for each lot (batch) of vaccine after approval.

FDA Review Staff

FDA carefully and thoroughly evaluates data and information about the vaccine. A typical FDA review team is comprised of physicians, chemists, statisticians, pharmacologists/toxicologists, microbiologists, experts in postmarketing safety, manufacturing and facility investigators, as well as labeling and communications experts.

FDA Inspections

The FDA's expert investigators inspect manufacturing facilities to carefully examine and evaluate the process used to make the vaccine to determine compliance with FDA's requirements. Manufacturing facilities are inspected before a vaccine can be approved, and then on a routine basis following approval.

Biologics License Application (BLA)

After phase 3 clinical trials meet specified milestones and the manufacturer develops a commercial manufacturing process, the manufacturer submits a BLA to the FDA. A BLA may be hundreds of thousands of pages or more and includes preclinical and clinical data, and details of the manufacturing process and the facility.

Continued next page...

FDA VACCINE FACTS

www.fda.gov/vaccines

#FDAVaccineFacts

Continued from previous page...

FDA Approval

The FDA evaluates hundreds of thousands of pages or more of data and manufacturing information as part of a BLA. If the FDA determines the vaccine is safe and effective for its intended use, that its benefits outweigh its risks for the people who are likely to get the vaccine, and the manufacturing process assures product quality and consistency, the FDA will “license” (or approve) the vaccine.

Vaccine Safety Surveillance

The FDA, in collaboration with other federal agencies, academic and large non-government health care systems, uses both passive and active surveillance systems to monitor the safety of vaccines after approval. These systems include the Vaccine Adverse Event Reporting System (VAERS), the FDA Sentinel BEST (Biologics Effectiveness and Safety) program, a partnership with the Centers for Medicare and Medicaid Services to assess Medicare claims, and the CDC’s Vaccine Safety Datalink.

Lot Release

Manufacturers are not permitted to distribute a specific lot (batch) of vaccine until the FDA releases it. To release a vaccine lot, the FDA reviews the manufacturer’s test results that typically include vaccine sterility, purity, potency, and consistency, and may perform confirmatory testing.

Vaccines and Related Biological Products Advisory Committee (VRBPAC)

Sometimes the FDA seeks the input of the VRBPAC, a federal advisory committee. VRBPAC is a panel of outside, independent, scientific and public health experts. The FDA considers, but is not bound by, the VRBPAC’s recommendations.

Prescribing Information and Labeling

Based on scientific data submitted in the BLA, the FDA reviews and determines whether the prescribing information adequately and accurately reflects the approved indication(s), usage, dosing, and administration. Prescribing information is updated as needed in order to include the most current information about the vaccine that is available and reviewed by the FDA.

Phase 4 Clinical Trials

In some cases the FDA requires a manufacturer to conduct post-marketing studies or Phase 4 clinical trials to further assess known or potential serious risks of the vaccine.

FDA Regulatory Research

Ongoing research is fundamental to the FDA’s ability to provide effective vaccine regulation. FDA scientists conduct a variety of research that contributes to policy, risk assessments, new methods and standards, and changes to product labeling, including promoting new techniques for assessing vaccine safety, potency, and effectiveness in addition to strategies for new vaccine development.