

Vaccine Safety Monitoring

Vaccine Safety

Vaccines are the best way to prevent serious illnesses and death from many infectious diseases. (Get [Quick Facts and Resources for Kentucky Residents](#).) The [Food and Drug Administration \(FDA\)](#) adheres to rigorous testing standards before licensing vaccines.

Vaccines are developed through the same general process used to develop drugs and medicines.

Vaccine Development 101

A sponsor who wishes to begin clinical trials with a vaccine must apply to the FDA. In their application, they must describe the vaccine, how it is manufactured, and the quality control tests that are done. The applications must also include information about the vaccine's safety and the results of testing in animals.

If the application is approved the vaccine can be tested on people during clinical trials. These trials are typically done in three phases. Phase 1 studies are performed in a small number of closely monitored subjects. Phase 2 studies may enroll hundreds of subjects. Phase 3 trials typically enroll thousands of people. These trials are used to document vaccine effectiveness. They also provide important additional safety data required for licensing. At any stage of the studies in animals or humans, if data raise significant concerns about either safety or effectiveness, the FDA may request additional information or studies, or may halt ongoing clinical studies.

After reviewing clinical trial results and the proposed vaccine label, inspecting the facility where the vaccine will be made, and reviewing the vaccine production process, the FDA may decide to license the vaccine. The FDA also authorizes Emergency Use when justified. Find out more about [Emergency Use Authorizations](#).

Once licensed, vaccines continue to be closely monitored through the national Vaccine Adverse Event Reporting System (VAERS) and Vaccine Safety Datalink (VSD) Project.

Vaccine Trial in Kentucky

In Kentucky, the University of Kentucky, partnering with Baptist Health Lexington and Norton Healthcare in Louisville, are conducting a [clinical trial](#) for a potential COVID-19 vaccine for Janssen Pharmaceutical Companies of Johnson & Johnson's phase three clinical study. The study will evaluate Janssen's COVID-19 vaccine candidate.

Questions about the Vaccine

People with more questions or concerns about vaccine safety should contact their healthcare providers. Information found online should not replace the information given by a health care provider. However, there are several trusted organizations that parents, guardians and patients can turn to for additional information.