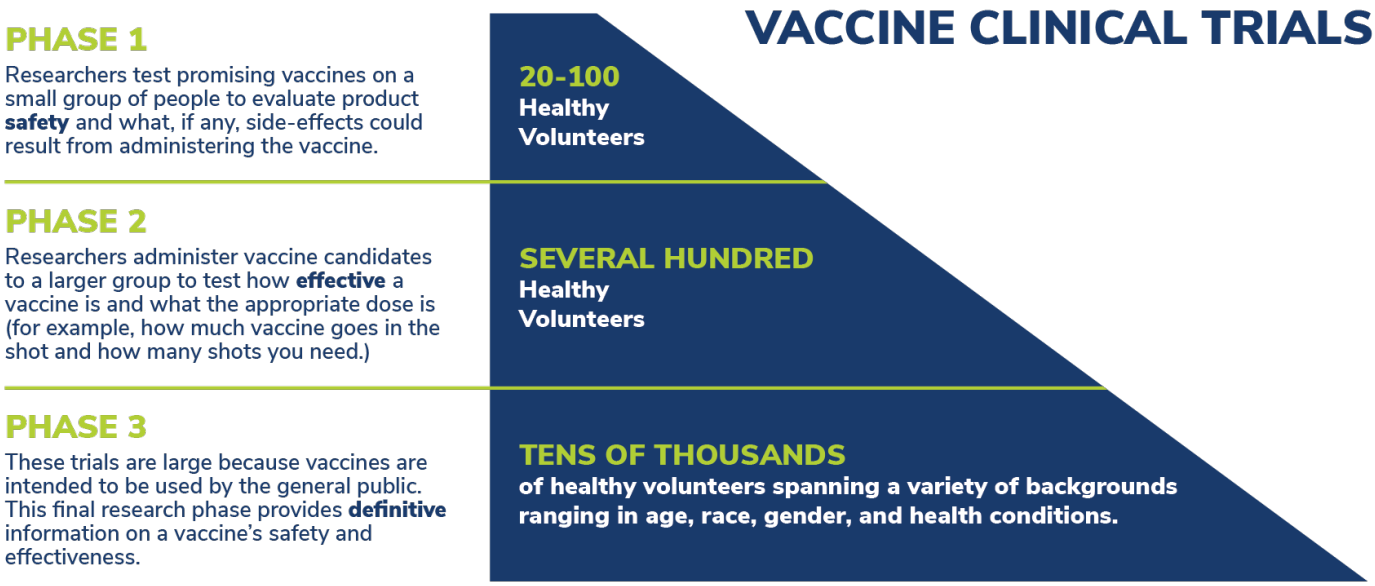
Understanding the COVID-19 Vaccines

The Food and Drug Administration (FDA) recently issued Emergency Use Authorization for the first vaccines in the United States to prevent COVID-19. Development and authorization of these vaccines occurred in record time, leading some to question the safety and effectiveness of these life-saving developments. It's critical that Iowans understand the vaccine development process and trust that these vaccines are safe. If you have questions about the vaccines, your local doctor and public health officials are here to help with the information you can trust. As we look forward to enough COVID-19 vaccines being available for everyone, remember to continue observing the COVID-19 safety measures to protect yourself, your loved ones, and your communities.

Vaccine Development

Like all new medicines or treatments, vaccines must pass a rigorous set of tests before being approved by independent, scientific experts at the FDA. In fact, the vaccine development process is so difficult that only one out of every five experimental vaccines are successfully approved for use.



Only after completing all three phases of clinical trials can a vaccine apply for approval by the FDA. Participants in the clinical trials will continued to be monitored for at least two years after the conclusion of the study to track long-term safety and effectiveness of the vaccine.

Emergency Use Authorization

Emergency Use Authorization (EUA) is a special approval the FDA grants to make new treatments and vaccines available during public health emergencies like the COVID-19 pandemic. Manufacturers must still submit extensive documentation to demonstrate the safety and effectiveness of a treatment or vaccine under consideration. With the COVID-19 vaccines, the FDA required a minimum of two months of data from the large Phase 3 trials before a vaccine could be considered for Emergency Use Authorization. This EUA process dramatically speeds up the approval process by moving applications to the front of the line for FDA consideration and reducing the required documentation manufacturers must submit. Independent scientific experts must still review the data from the clinical trials to determine if a vaccine is safe and effective before approving an EUA.

Is the COVID-19 Vaccine Safe?

Yes. The FDA evaluates all vaccines to ensure they meet the following criteria prior to approving an EUA:

- Safe for use following a series of random, placebo-based clinical trials of thousands of people.
- Shown to be effective at preventing the disease.
- Proven to be produced or manufactured consistently, safely, and at a high quality.

Independent Oversight

There are multiple layers of independent oversight built into the vaccine development process.

- **Institutional Review Boards**, consisting of health and scientific experts, oversee all clinical trials to protect rights and safety of trial participants. They have authority to approve or disapprove of a clinical study, or require changes to the research. The review board's decisions are guided only by what is best for clinical trial participants. COVID-19 vaccine trials at locations including the University of Iowa and the Iowa Clinic are overseen by separate Institutional Review Boards at each facility.
- **Data Safety Monitoring Boards** are independent experts that include biologists, immunologists, statisticians, and health professionals. They analyze real-time data during the clinical trial process, offering advice and expertise about if and how a trial should move forward or whether one should be paused. These experts provide unbiased evaluation to make sure safety and efficacy rules are being followed and concerns are being addressed along the way.
- **The Vaccines and Related Biological Products Advisory Committee** is a group of 15 independent voting members within the FDA who are knowledgeable in fields such as immunology, molecular biology, virology, bacteriology, epidemiology, vaccine policy, vaccine safety science, vaccine development, medicine, and infectious diseases, as well as a consumer representative. Following the conclusion of a clinical trial, this advisory committee will review the data for the specific vaccine and make a recommendation to the FDA as to whether the product should be authorized for use.
- **The Advisory Committee on Immunization Practices (ACIP)** is a group of independent medical and public health experts that advise the Centers for Disease Control and Prevention (CDC). This committee also reviews the safety and efficacy data from the vaccine clinical trials. Following the FDA's approval of a vaccine, this committee conducts a final review of the safety and effectiveness of the vaccine to make recommendations about who should receive a vaccine and when.

Iowans Involved in Vaccine Development

Coronavirus research at the University of Iowa contributed to the scientific foundation upon which this new vaccine was developed. The University of Iowa Hospitals and Clinics participated in the Phase 3 clinical trials for the Pfizer-BioNTech COVID-19 vaccine, which was granted Emergency Use Authorization on December 11. The Iowa Clinic is currently participating in Phase 3 clinical trials for the AstraZeneca vaccine candidate. Iowa physicians are overseeing these clinical trials and hundreds of Iowa patients have volunteered to participate in these critical studies to ensure the safety and effectiveness of the vaccines. On December 14, Iowa began receiving the first doses of the Pfizer-BioNTech vaccine and clinical staff across the state volunteered to receive the first doses themselves. Our local providers know the rigorous review and approval process for a COVID-19 vaccine can be trusted to keep them and their patients safe.

Questions About the COVID-19 Vaccine

It's normal to have questions about a new treatment or vaccine. Your local healthcare providers and public health officials remain your best source for answers you can trust. The Iowa Department of Public Health also has extensive resources on its COVID-19 Vaccine Information website to help.