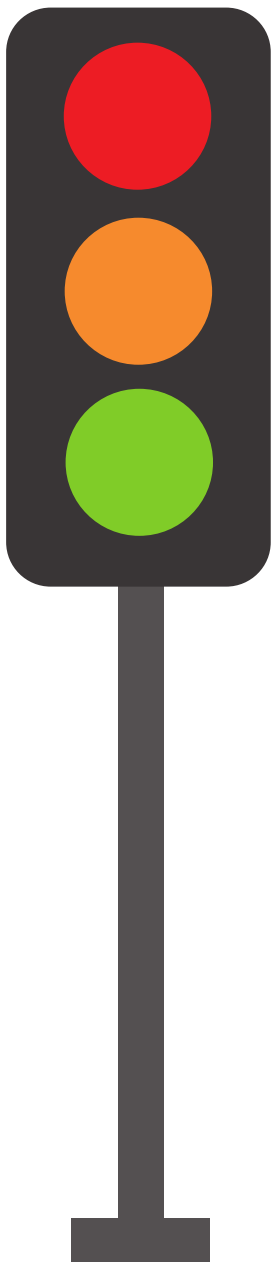




# Vaccine Safety

## A System of Safeguards from Development through Delivery and Beyond

Vaccines are widely considered to be one of this century's greatest public health and scientific achievements. [1,2] Safety is critically important in vaccines because they are a preventive treatment given to healthy people, often children and infants. [3]



**New vaccines are created through a comprehensive, standardized process with safeguards in place at every step.**

- Regulation and oversight increase as a new vaccine moves forward through this development process. [4]
- The vaccine safety system is continually updated and improved as knowledge and science progress, ensuring vaccines are as safe as possible. [5]

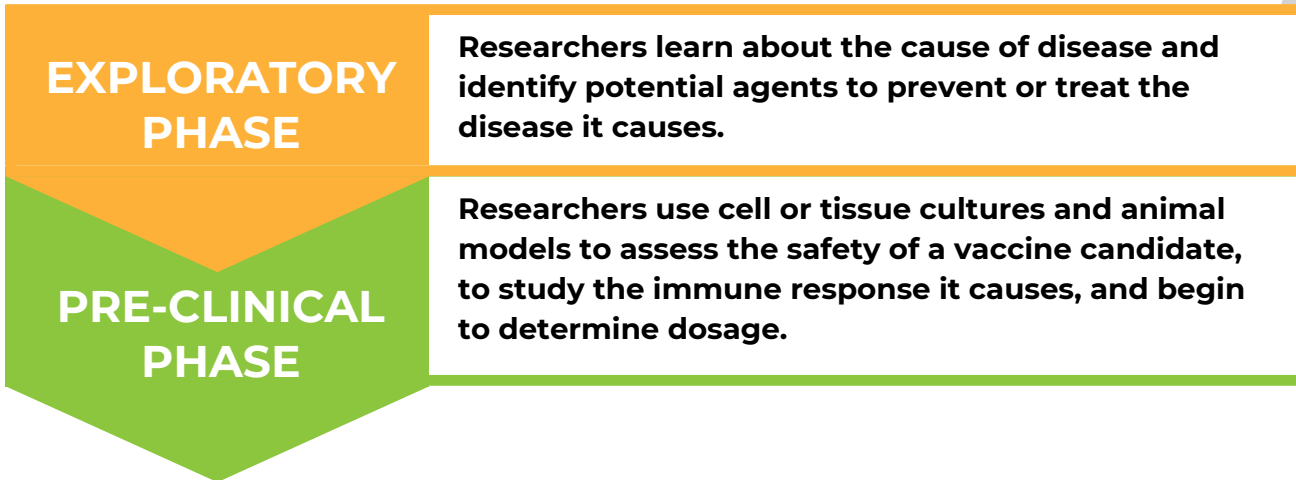
### **EVERY NEW VACCINE GOES THROUGH:**

- **Exploratory Phase**
- **Pre-clinical Phase**
- **Investigational New Drug Application**
- **Phase I-III Clinical Trials**
- **Approval and Licensure**
- **Ongoing Post-licensure Monitoring**

**This developmental process is so rigorous that only 1 out of every 5 experimental vaccines is approved for use.**

# A CLOSER LOOK AT SAFETY IN VACCINE DEVELOPMENT

Before a new vaccine is tested in humans it goes through exploratory and pre-clinical stages.



## PHASE 1

Researchers test promising vaccines on a small group of people to evaluate product safety and what, if any, side-effects could result from administering the vaccine.

**20-100**  
Healthy  
Volunteers

## PHASE 2

Researchers administer vaccine candidates to a larger group to test how effective a vaccine is and what appropriate dose is (for example, how much vaccine goes in the shot and how many shots you need).

**SEVERAL HUNDRED**  
Healthy Volunteers

## PHASE 3

These trials are large because vaccines are intended to be used by the general public. This final research phase provides definitive information on a vaccine's safety and effectiveness.

**TENS OF THOUSANDS**  
Of healthy volunteers spanning a variety of backgrounds ranging in age, race, gender, and health conditions.

## VACCINE CLINICAL TRIALS

## ONGOING MONITORING

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.

### Sources:

- [1] Achievements in Public Health, 1900-1999 Impact of Vaccines Universally Recommended for Children -- United States, 1990-1998. (1999, April 2). Retrieved November 17, 2020, from <https://www.cdc.gov/mmwr/preview/mmwrhtml/00056803.htm>
- [2] Vetter, V., Denizer, G., Friedland, L. R., Krishnan, J., & Shapiro, M. (2018). Understanding modern-day vaccines: what you need to know. *Annals of medicine*, 50(2), 110-120. <https://doi.org/10.1080/07853890.2017.1407035>
- [3] Singh, K., & Mehta, S. (2016). The clinical development process for a novel preventive vaccine: An overview. *Journal of postgraduate medicine*, 62(1), 4-11. <https://doi.org/10.4103/0022-3859.173187>
- [4] Vaccine Development, Testing, and Regulation. (2018, January 17). Retrieved November 17, 2020, from <https://www.historyofvaccines.org/content/articles/vaccine-development-testing-and-regulation>
- [5] Ensuring Vaccine Safety. (2020, July 01). Retrieved November 17, 2020, from <https://www.cdc.gov/vaccinesafety/ensuringsafety/index.html>



Iowa Immunizes is a coalition of individuals and organizations committed to protecting the health of Iowans through vaccination of children and adults. Iowa Immunizes is supported by Iowa Public Health Association. [www.iowaimmunizes.org](http://www.iowaimmunizes.org)

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