

# VACCINE DEVELOPMENT, LICENSURE & SAFETY

The creation of a vaccine involves scientists and medical experts from around the world, and it usually requires **10 to 15 years of research** before the vaccine is made available to the general public.<sup>1</sup>

## Safety is a priority at every stage of vaccine development.<sup>2</sup>

## **Vaccine Development**

Clinical Development	Regulatory Review and Approval	Manufacturing
Clinical trials generally involve three phases of research studies in humans to evaluate the safety and efficacy of a vaccine, with each phase growing by more and more volunteers. By the time a vaccine is up for approval, tens of thousands of people have participated and definitive safety information has been established.	Through a rigorous data review process, experts at the Food & Drug Administration (FDA) determine whether a vaccine is safe, effective, and can be manufactured at a high quality and on a consistent basis. Only after these criteria are met, FDA will provide its stamp of approval.	Manufacturers work to ensure they adhere to the highest quality manufacturing standards and routinely verify the quality of the vaccine being produced. This quality is then verified separately by the FDA for each lot produced.

#### **Vaccine Licensing**

FDA licenses a vaccine only if it is safe and effective and its benefits outweigh any risks.<sup>3</sup> In some cases, FDA seeks advice from an external advisory committee to assist in assessing benefits and risks. The Vaccines and Related Biological Products Advisory Committee (VRBPAC) is a panel of outside, independent, technical experts from various scientific and public health disciplines that provide input on scientific data and its public health significance in a public forum. Its input is considered by FDA, but is not binding when determining whether to approve a vaccine.

#### **Recommendations for Use of Vaccines**

A vaccine receives a recommendation from the Centers for Disease Control & Prevention (CDC) only after FDA approves and licenses it. Healthcare professionals seek guidance from the Advisory Committee on Immunization Practices (ACIP), a group of independent medical and public health experts who develop vaccine use recommendations and schedules. An ACIP recommendation does not mean that a vaccine is required for use. State legislatures and health departments determine whether a vaccine is required.



### Vaccine Safety Monitoring

After a vaccine is licensed, its safety continues to be monitored. CDC, FDA and numerous US university medical centers and health organizations have systems and approaches to watch for adverse events (or side effects) and assure that possible risks associated with use of the vaccine by the public are identified.

- Vaccine Adverse Event Reporting System (VAERS)
  - Analyzes reports of adverse events that happen after vaccination. Anyone can submit a report to VAERS, and submissions do not mean that a vaccine definitely caused the event.
- Vaccine Safety Datalink (VSD)
  - Analyzes healthcare information from more than 24 million people in group form (protects an individual's confidentiality)
- Post-Licensure Rapid Immunization Safety Monitoring (PRISM)
  - Analyzes healthcare information from more than 190 million people in group form (protects an individual's confidentiality)
- **Clinical Immunization Safety Assess (CISA) Project** 
  - CDC collaborates with 7 medical research centers that provide expert technical advice and research focused on vaccine safety and decreasing side effects
- **Emergency Preparedness for Vaccine Safety** 
  - Activated by CDC in event of disease outbreak in which mass vaccination programs are needed

#### Making a Vaccine

Vaccines against various viruses and bacteria are designed and manufactured in different ways.<sup>4</sup> Approaches for different types of vaccines include:



New York State, Department of Health. The Science Behind Vaccine Research and Testing. https://www.health.ny.gov/prevention/immunization/vaccine\_safety/science.htm

- <sup>2</sup> CDC: Overview, History, and How the Safety Process Works. https://www.cdc.gov/vaccinesafety/ensuringsafety/history/index.html
- <sup>3</sup> Journey of Your Child's Vaccine. Centers for Disease Control. https://www.cdc.gov/vaccines/parents/infographics/journey-of-child-vaccine-h.pdf <sup>4</sup> Children's Hospital of Philadelphia, Vaccine Education Center, Making Vaccines: How Vaccines are Made (Infographic). https://www.chop.edu/centers-programs/vaccine-education-center/making-vaccines/how-are-vaccines-made
- <sup>5</sup> Principles of Vaccination, A. Patricia Wodi, MD and Valerie Morelli, BA https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/prinvac.pdf
- <sup>6</sup> History of Vaccines. Different Types of Vaccines. https://historyofvaccines.org/vaccines-101/what-do-vaccines-do/different-types-vaccines <sup>7</sup> CBER. Vaccine Development 101. https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101
- 8 https://www.genomicseducation.hee.nhs.uk/blog/why-mrna-vaccines-arent-gene-therapies/

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