Pfizer Logo

Vaccine Production: Find Out How Vaccines Are Created

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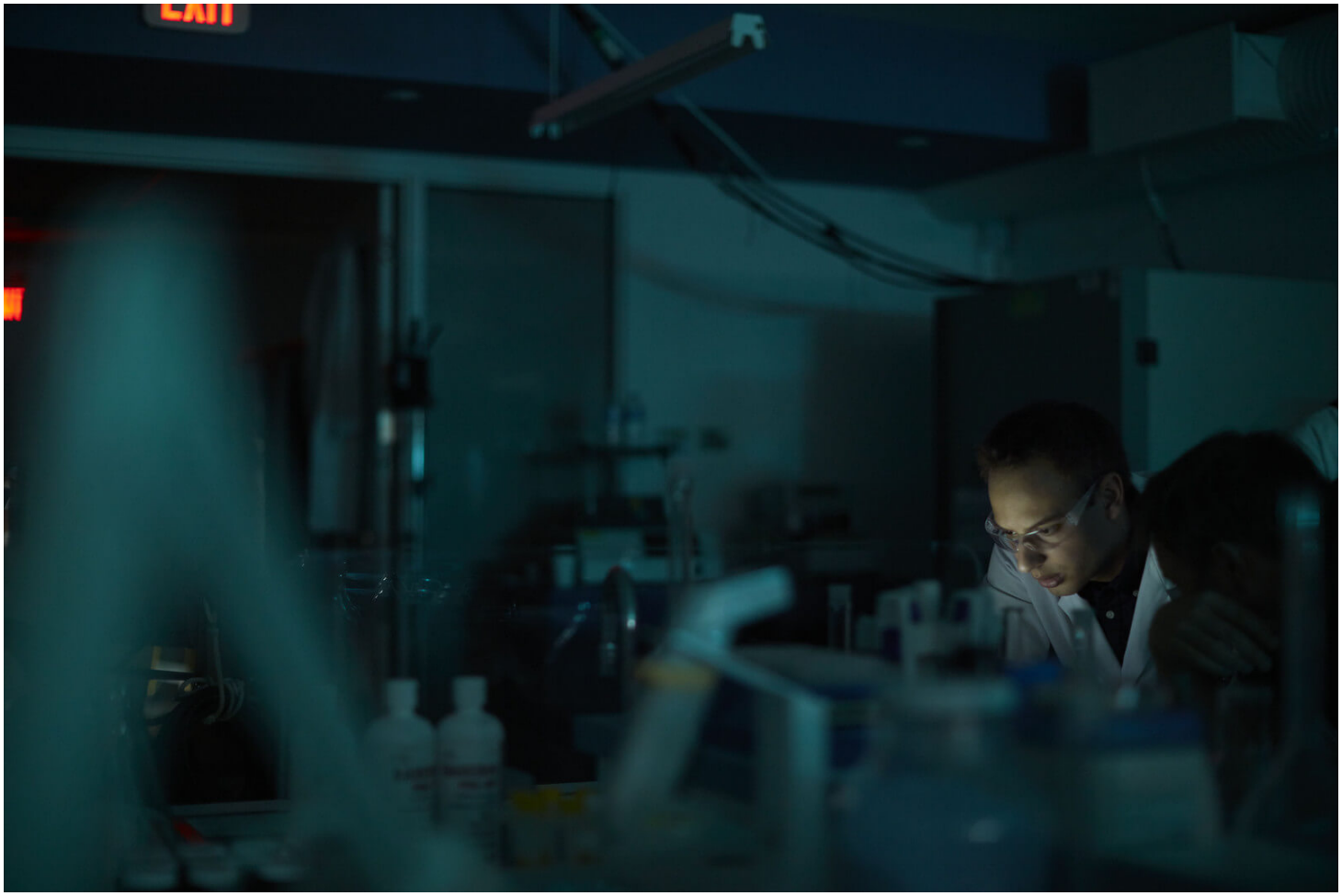

Vaccines have revolutionized our ability to improve health and save lives, resulting in the control, elimination, or near-elimination of many life-threatening diseases. The path to disease prevention – the development of a novel vaccine – is a complex and lengthy process that generally takes 10 to 15 years.[1] Every step of the way, our team is committed to pursuing research and forming partnerships that facilitate the rapid development and delivery of a vaccine. To help protect against the COVID-19 pandemic, one such partnership is already underway with the goal of bringing forward a safe and effective vaccine with unprecedented urgency.

A Typical Vaccine Roadmap

Step 1: Exploratory – Research

Usually, laboratory research is conducted for 2 to 5 years to identify antigens to include in a vaccine.[1]

Step 2: Preclinical – Safety & Efficacy

Researchers conduct testing to assess vaccine candidates' immunogenicity, their ability to elicit the desired immune response. Other areas of focus include short-term toxicology, formulation, and development of a scalable, efficient, and reproducible manufacturing process. This data collection and analysis can take around 2 years. [1]

Step 3: Clinical – Safety & Efficacy in Humans

In the United States, an application for an Investigational New Drug (IND) is submitted to the U.S. Food and Drug Administration (FDA). Only with an approval of the IND by the FDA does the potential vaccine proceed through 3 phases of testing in humans.[2,4]

- **Phase 1** (2 years) – Typically, less than 100 volunteers are administered the candidate vaccine in a non-blinded study to determine whether it is safe to proceed to Phase 2, and to determine whether a sufficient immune response is provoked.[1,2]

- **Phase 2** (2 to 3 years) – A larger group of subjects receive the vaccine candidate; the safety, immunogenicity, doses, immunization schedules, and delivery methods are studied.[1]

- **Phase 3** (5 to 10 years) – This randomized, placebo-controlled, blinded pivotal study generally involves thousands of people in whom vaccine safety and efficacy are tested. This trial generally includes monitoring potential side effects in subjects, determining whether the vaccine candidate can help to prevent disease, and testing whether it leads to the production of antibodies against the specific pathogen.[1,2]

Step 4: Regulatory Review & Approval – Licensure

If the candidate vaccine is determined to be safe and effective, a Biologics License Application (BLA) is submitted to the FDA, which may conduct its own testing. The FDA also inspects the production of the vaccine candidate and monitors its potency, safety, and purity; this entire process could take up to 2 years.[2,4]

Step 5: Production – Scaling Up

Manufacturing scales up production of large quantities of the vaccine, ensuring all product meets the necessary regulatory requirements, including current Good Manufacturing Processes (cGMP).[2]

Step 6: Quality Control – Performance Review, Post-Marketing

The vaccine is continuously tracked and monitored for its performance, safety, and effectiveness through pharmacovigilance conducted after the product is released into the market.[2,4]

WHAT ARE THE STEPS TO DEVELOPING A VACCINE?

STEP 01

RESEARCH

STEP 02

PRECLINICAL

STEP 03

CLINICAL

STEP 04

REGULATORY

References

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