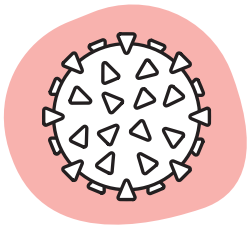
VACCINE 101

How Vaccines are Developed and Approved

We understand we're not all public health experts and there's a lot of jargon, so here are some keywords:

Placebo: A substance that has no medical effect. It is given to patients in clinical trials to give researchers a group to compare with the actual trial medication.

Efficacy: The percentage of disease a medication can prevent. For example, if 100 people receive a vaccine and 5 people get the disease it is supposed to prevent, the vaccine is 95% efficacious.



DISCOVERY PHASE

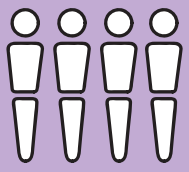
Identify the pathogen & characterize the pathogen's structure

The purpose of a vaccine is to train the human body to create an effective immune response before serious infection can take place. To create that immune response, the body has to be exposed to the pathogen. A vaccine allows us to safely expose the body to key parts of pathogens that have been identified. In the case of SARS-COV-2 that was done first in 2019 in Wuhan, China. Luckily, we have the technology to rapidly study viruses to determine their structure and genetic makeup. There are four main components to SARS-COV-2: the spike protein, envelope, nucleocapsid, and the membrane.

PRECLINICAL PHASE

Experiment with vaccine types in different animals

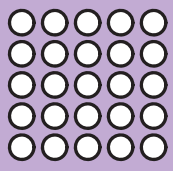
Once the structure of the virus is understood, we can start learning how to attack it. This can be done in different ways but is usually done using animals such as monkeys or mice. It has been determined that the spike protein of SARS-COV-2 elicits a strong immune response. To make an effective vaccine, scientists had to figure out how to expose our cells to this section of SARS-COV-2.



PHASE 1

Safety trial in a small number of people & initial efficacy test

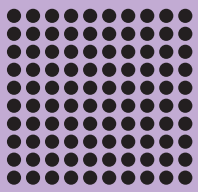
Phase 1 is primarily concerned with safety. The vaccine is given to a small number of people to observe side effects and to confirm it is stimulating an immune response. Common side effects of vaccines include soreness at the injection site, fatigue, and low fevers due to the immune system reacting to the sections of the pathogen in the vaccine.



PHASE 2

A larger number of people, comparing different people, & further evaluating safety and efficacy

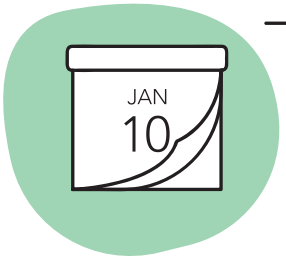
The vaccine is then administered to hundreds of people and results are analyzed to look for differences between groups, such as young adults vs. the elderly or men vs. women. The trial also further assesses safety and efficacy.



PHASE 3

The largest amount of people, placebo vs vaccine, clinical endpoint, & dosage, safety, and efficacy

This is the largest trial. Tens to hundreds of thousands of people around the world are enrolled in phase 3 trials in this phase of testing. These trials are the basis of determining the efficacy of the vaccine as participants are given either the vaccine or a placebo. In the world of vaccine trials, clinical endpoint analysis, which examines if people in each group got infected and displayed specified symptoms, allows drugmakers to report efficacy. Clinical endpoint analysis is performed by comparing the number of people who became symptomatic with the disease with their vaccine status. Ideally, most infections would occur in people that received the placebo, which would indicate high efficacy. Due to a large number of participants, rarer side effects are able to be teased out and assessed, such as allergic reactions or joint pain.



APPROVAL

Data submitted to regulatory agencies, which may expedite the process in emergencies based on limited review

Regulatory agencies review the data presented by the drug companies and make a decision on whether or not to grant approval. Typically the process can last 3-10 months depending on the type of drug presented. However, the FDA can issue the Emergency Use Authorization (EUA) based on a limited review of just a couple of weeks to allow the drug to enter the market more quickly. This is how some COVID treatments and diagnostic tests have been approved. The entire review process still takes place after the EUA and the drug companies continue to look for adverse effects, conduct post-market trials, and are subject to manufacturing audits by regulatory agencies.