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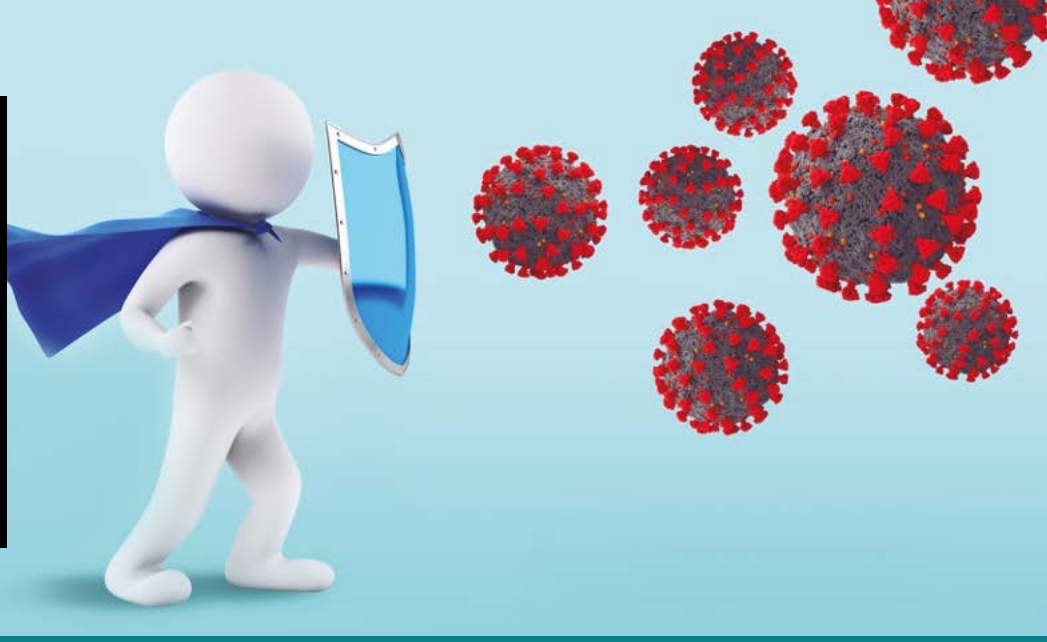

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DEVELOPING A CORONAVIRUS VACCINE – THE MOST URGENT SHARED ENDEAVOR OF OUR LIFETIMES: PART 1

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HOW DOES A VACCINE WORK?

Vaccines reduce the risk of disease by preparing the immune system – the body's natural defense system – to recognize, fight and destroy viruses and bacteria which can cause serious illnesses. Traditionally vaccines have been produced using a virus which has either been weakened or deactivated and they are grown in eggs or cell cultures. When a vaccine is given the body mounts an immune response and certain cells remain that will recognize the virus if a future exposure occurs, protecting against development of the disease.

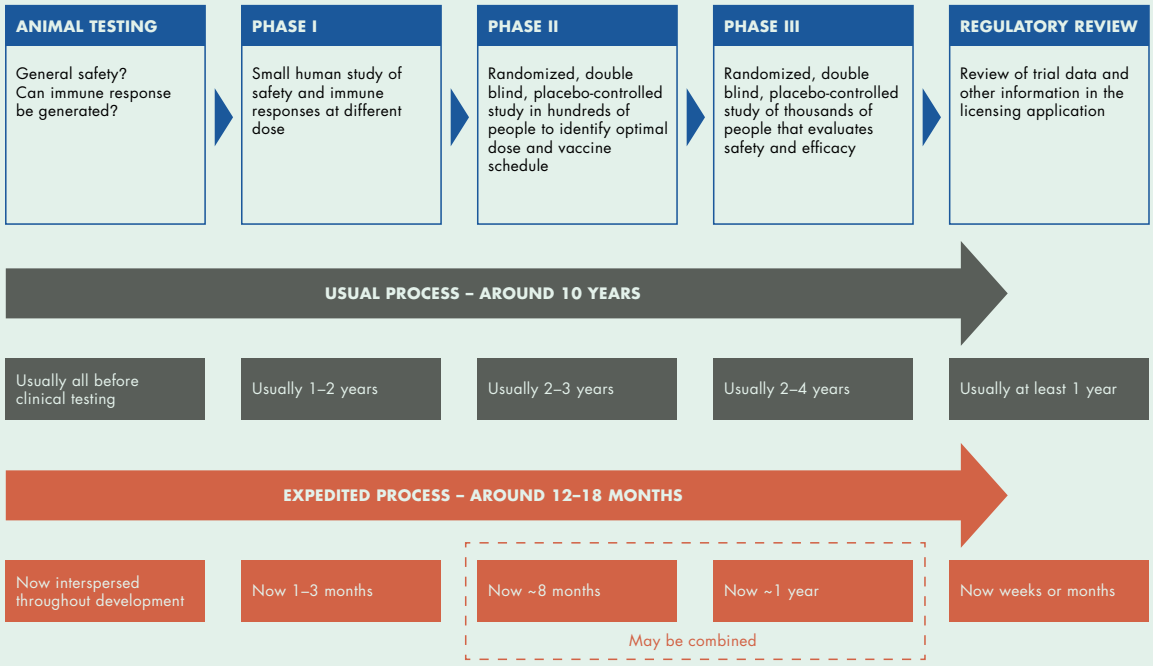
An alternative approach is to genetically engineer a virus (usually an adenovirus [common cold virus]) to produce coronavirus proteins in the body, or to introduce an element of the coronavirus directly, such as the so-called virus spike protein. Another newer type of vaccine is a DNA or RNA-based vaccine. These vaccines do not contain virus or elements of virus and can be produced quickly and reliably in a laboratory. However, unlike vaccines made from whole organisms and that mimic the protective immune responses seen in nature, these "next generation" vaccines require a reasonable understanding of the human immune response to the pathogen, what particular parts of the pathogen are responsible for provoking protective immunity, and what type of vaccine delivery systems can generate that specific protective immune response.

You can find more information about different types of vaccines, about DNA vaccines and RNA vaccines by following these links.

WHAT IS THE PROCESS FOR DEVELOPING A VACCINE AGAINST COVID-19 AND CAN IT BE SPED UP?

Companies around the world are attempting to make an effective vaccine against COVID-19. The benefit of developing and trying multiple potential vaccines is the increased chance that one of them will be found to be safe and effective and be approved for use. First, however, they must go through clinical trials.

HOW TO EXPEDITE THE VACCINE DEVELOPMENT PROCESS



As vaccines are given to potentially millions or hundreds of millions of healthy people, the most important element in clinical testing is to ensure that the vaccine is safe. The process from discovery to approval usually takes around 10 years, but because of the urgent need for a COVID-19 vaccine, governments, academic institutions, regulatory bodies, and industries are joining forces and making efforts to expedite the process as follows:

- Animal (preclinical) testing – to be interspersed throughout vaccine development so a vaccine can enter the clinic more quickly. Testing in animals can give an initial understanding of the general safety of the vaccine and if it can generate the right type of immune response
- Phase I: A small study in healthy people that evaluates the vaccine for safety and immune response at different doses. For COVID-19 trials, this is expected to take 1–3 months; under usual circumstances it typically takes 1–2 years
- Phase II: A randomized, double blind, placebo-controlled study of hundreds of people that further evaluates safety, assesses immunogenicity, efficacy and informs optimal dose and vaccine schedule. For COVID-19 trials, this is expected to take about 8 months; it can typically take 2–3 years
- Phase III: A randomized, double blind, placebo-controlled study of thousands of people that evaluates safety and efficacy. For COVID-19 trials, this may be combined with Phase II; usually this is the longest stage of the development process and takes 2–4 years
- Regulatory review: The governmental body that approves new vaccines reviews the trial data and other information in the licensing application. The normal review timeline for a vaccine is around a year, but this is likely to be expedited to take only weeks or months
- Phase IV: Post approval studies that monitor safety and effectiveness in real world conditions and will detect unusual side effects which may only be seen when the vaccine has been given to many thousands or millions of people

So overall this means that, despite efforts from all stakeholders, it will likely take at least a year from development of a vaccine to it being approved and available for widespread use to prevent COVID-19.

HOW ARE KEY ORGANIZATIONS, COLLABORATIVE GROUPS AND PHILANTHROPIC INDIVIDUALS TRYING TO EXPEDITE COVID-19 VACCINE DEVELOPMENT?

Around the world, it has been recognized that collaboration is key to defeating the COVID-19 pandemic. A number of different stakeholders are involved, committing time, brain power and money to develop diagnostics, treatments and vaccines. As of late May 2020, the below organizations have disclosed their support for various initiatives.

The Coalition for Epidemic Preparedness Innovations (**CEPI**) is an innovative partnership between public, private, philanthropic, and civil organizations, launched at Davos in 2017, to develop vaccines to stop future epidemics. CEPI's mission is to stimulate and accelerate the development of vaccines against emerging infectious diseases and enable access to these vaccines for people during outbreaks.

Between 23 January and 27 April CEPI has provided initial support and funding to nine organizations: Curevac, Inc., Inovio Pharmaceuticals, Inc., Moderna, Inc., Novavax, Inc., The University of Hong Kong, The University of Oxford, The University of Queensland, Institut Pasteur and Clover Pharmaceuticals Australia to develop COVID-19 vaccine candidates.

The Global Alliance for Vaccines and Immunisation, today Gavi, the Vaccine Alliance was formed in 2000 and shares the cost developing countries pay for vaccines, which has resulted in more than 460 vaccine campaigns and dramatically boosted immunization against virulent diseases. Gavi has been providing urgent initial funding to 13 lower-income countries to support their response to COVID-19 and is working to maintain ongoing immunization programmes as well as bringing its unique expertise to COVID-19 vaccine development initiatives.

The Biomedical Advanced Research and Development Authority (BARDA) is a division of the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS). BARDA is responding to the pandemic threat by supporting research, approval and manufacture of vaccines, drugs and diagnostics for COVID-19.

The **WHO** continues to provide rolling updates on the pandemic, as well as many useful resources. It recently announced a landmark global collaboration – the Access to COVID-19 Tools Accelerator, or the ACT Accelerator, bringing together WHO, CEPI, GAVI and other stakeholders to accelerate the development, production and equitable global access to new COVID-19 essential health technologies.

It has been recently reported that the Trump administration is organizing a Manhattan Project-style effort to drastically cut the time needed to develop a coronavirus vaccine, with a goal of making enough doses for most Americans by year's end. Labelled "Operation Warp Speed," the program will bring together pharmaceutical companies, government agencies and the military to try to cut the development time for a vaccine and provide millions of doses of vaccine by the end of 2020.

Bill Gates has been taking a keen interest in the development of a COVID-19 vaccine and the **Bill and Melinda Gates Foundation** has deep expertise in infectious diseases. Gates has committed to funding manufacturing capability for leading vaccine candidates, even if it goes unused. In a recent blog he discusses COVID-19 vaccine development and anticipates that at least 7 billion vaccine doses may be needed

Finally, pharmaceutical companies and contract manufacturing organizations have already begun manufacturing large amounts of vaccine doses even before the vaccines are tested in people. These companies are manufacturing "at risk" to ensure that if a vaccine is successful that enough of it has already been produced to meet the initial public health need.