University at Buffalo Clinical and Translational Science Institute

The Creation of a Vaccine Human studies progress in PHASES to ensure safety.



CLINICAL TRIAL PHASE 1

- Focus on safety
- Learn about dosage and possible side effects
- Small group of volunteers.
- If no serious side effects are found, they move to Phase 2



CLINICAL TRIAL PHASE 3

 Hundreds or thousands of volunteers participate

VACCINE DEVELOPMENT

Vaccine development begins in the laboratory and then if there is potential for the vaccine it may be tested in animals. Only after it is determined to be safe in animals will it move on to human studies.



CLINICAL TRIAL PHASE 2

- Involves several hundred volunteers
- Assess short-term side effects and how the size of the dose relates to immune response
- Some people receive the vaccine and some receive a placebo
- These two groups are compared for safety, effectiveness and side effects



FDA REVIEW

The Food and Drug Administration (FDA)

- Requires that clinical trials are run at the highest scientific and ethical standards
- Evaluates the results of all completed studies to assess the safety and effectiveness of each vaccine

Approved Vaccine

FDA scientists and medical professionals carefully evaluate a wide range of information to ensure that the new vaccine can be made consistently safe, pure, and potent.

Information from www.cdc.gov/vaccines



Advancing research discoveries to improve health for all

Did You Know?

Vaccines help to prevent dangerous diseases. Vaccines work with the body's natural defenses to safely develop immunity to disease.

Some vaccines are made by inactivating, or killing, the germ during the process of making the vaccine. The COVID-19 vaccine is an inactive vaccine that may need to be taken several times or every year like the flu vaccine.

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Both getting a disease or getting a vaccine can give you future protection from that disease. The difference is that with the disease you have to get sick to get that protection. With the vaccine you do not.

You can get information on COVID-19 studies that are happening at the University at Buffalo here: research.buffalo.edu/portal/clinicaltrial/

Information from www.cdc.gov/vaccines

Questions to Ask Your Provider or Pharmacist

What are the side effects of this vaccine? How often do I need to get this vaccine? What are the ingredients of this vaccine?

Where can I get a vaccination?

What are the risks if I don't want to get the vaccine?

Does getting the vaccine make it safer for you to be around others who have COVID?

This program is supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under award number UL1TR001412 to the University at Buffalo.