COVID-19 VACCINE TRIALS Philippines

PRIMER

Must-Know on PH Vaccine Trials

10/05/20

Vaccine trials are important for managing the COVID-19 pandemic.

The next few months will be crucial as the world works towards developing a vaccine for COVID-19. However, there is still much that needs to be shared with the public. We hope that this primer provides readers with all the necessary information about the vaccine trials that are going to be conducted in the country. This primer will be updated as needed vis-a-vis important developments that will take place during the course of the vaccine trials.

COVID-19
VACCINE
TRIALS
Philippines

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I. Introduction to COVID-19 Vaccine Trials

What is a vaccine clinical trial?

- Clinical trials, a type of clinical research study, are medical studies that involve people.
- The process of evaluating the safety, immunogenicity, and protective efficacy in humans of a novel vaccine candidate before it can be licensed for use.
- Vaccine clinical trials explore whether investigational vaccines are safe and effective for humans.

How is a vaccine developed?

A vaccine candidate undergoes three phases of development in humans:

Pre-clinical

Vaccines are tested in animals such as mice and monkeys to see if it produces an immune response.

10-100

Phase 1

Vaccines are given to a small number of people (10-100 people) to test its safety.

100-1000

Phase 2

Vaccines are given to hundreds of people (100 to 1,000 people) to test its efficacy, determine the right dosage, and ensure that the desired effects are achieved.

Phase 3

Vaccines are tested in a larger group of people to confirm its efficacy and safety when compared to other treatments.

How do clinical trials work?

a) Clinical trials follow a plan, called a **protocol**, that describes what volunteers will be doing and what they can expect from the research team. The protocol is carefully designed to balance the potential benefits of a trial with the risks to participants. It also answers specific research questions, such as:

- i) Research objectives
- ii) Eligibility requirements
- iii) Protections against risks to participants
- iv) Details about tests, procedures, and treatments
- v) Expected duration, or how long the study will last
- vi) Information to be gathered

b) "Each clinical trial has criteria describing who can join. Children as well as adults, healthy volunteers and patients, and people of a diverse range of ethnic and racial backgrounds can and are encouraged to participate in clinical trials." (US-NIH)

c) **Placebo**: In a clinical trial, a volunteer is usually assigned a specific study group. Volunteers in one study group may receive the COVID-19 vaccine while others may receive a placebo or a comparator vaccine in order to assess its efficacy.

Why the need for clinical trials?

1) Every new vaccine, medicine, treatment, or preventive medical intervention started with volunteers participating in clinical trials. We owe our current high standards of medical care to studies that have been conducted in the past.

2) Clinical trials provide a scientific basis for advising and use of medical products for treating patients or preventing the possible occurrence of illnesses in people.

Are clinical trials safe?

The Food and Drug Administration (FDA) is the government agency responsible for regulating the conduct of clinical trials in the country. The FDA has regulations for clinical research to protect the participants from unreasonable risks. Before any clinical trial is allowed to be conducted in the country, a rigorous review process is followed by the FDA and partner evaluators to ensure the safety of the trials.

Aside from the Solidarity Trials, overseas clinical trials and prequalification from the WHO, the Philippine government has established additional measures to ensure vaccines safety and efficacy The sub Technical Working Group on Vaccine Development has created the DOST Vaccine Expert Panel, a group of technical experts and scientists tasked to identify, evaluate, and recommend possible vaccine candidates for the Philippines. The DOH Health Technology Assessment Unit as well as different medical and specialty societies have also suggested to the IATF safety nets to ensure vaccine safety when already in use through pharmacovigilance and surveillance.

Are there possible side effects?

Vaccination of investigational drugs or vaccines may have side effects including pain, redness, itchiness or swelling at the injection site, which may last a few hours. Other side effects may also include fever, feeling of weakness or fatigue, headache, dizziness, diarrhea, and nausea.

However, during the trial, the attending physician will determine if the side effects are causally related to the vaccines. Participants are also given diary cards and are expected to report to the vaccine trial monitors any side effects or development of COVID-19 signs and symptoms during the clinical trial period. Generally, the benefits of taking the vaccine outweigh the risks associated with its side effects.

Familiarize with the terms

Clinical Trial — any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes (WHO).

Vaccine — A substance which contain a microorganism or virus in a weakened, live or killed state, or proteins or toxins from the organism used to stimulate the production of antibodies and provide immunity against one or several diseases

Immunization — A process by which a person becomes protected against a disease through vaccination. This term is often used interchangeably with vaccination or inoculation

Vaccination — The act of introducing a vaccine into the body to produce immunity to a specific disease.

Placebo — An inactive substance or other intervention that looks the same as, and is given the same way as, a vaccine being tested. The effects of the vaccine or other intervention are compared to the effects of the placebo.

Protocol — is a document that describes how a clinical trial will be conducted (the objective(s), design, methodology, statistical considerations and organization of a clinical trial,) and ensures the safety of the trial subjects and integrity of the data collected

Immunity — Protection from an infectious disease. If you are immune to a disease, you can be exposed to it without becoming infected.

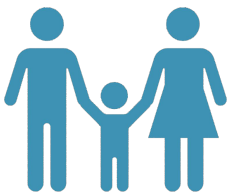
Volunteer — Is a person who takes part in a clinical trial.

Solidarity Trial — Pertains to the COVID-19 Vaccines Clinical Trials lead by the WHO which aims to harness a global cooperation to develop and evaluate vaccine candidates as quickly as possible to identify vaccine candidates and their progress; define the desired characteristics of safe and effective vaccines to combat the pandemic and coordinate the clinical trials across the world giving the best chance of safe and effective vaccines for all.

COVAX — The COVAX Facility, co led by Gavi, the Coalition for Epidemic Preparedness Innovations (CEPI), and the World Health Organization (WHO), is a platform that aims to accelerate the development and manufacture of COVID 19 vaccines and to ensure that every country in the world is able to access the successful vaccines.

II. Participation in Clinical Trials

Why participate in clinical trials?



LOVE FOR SELF AND FAMILY: Giving your "Yes" is crucial in our rapid search for COVID-19 vaccine. The information generated from your participation is valuable in order for the research to move forward. Successful or not the information is helpful in showing what didn't work and pushing research in a different direction.

LOVE FOR COUNTRY: When you participate in the trial, you are helping our country to have access to potential vaccine candidates.

SOLIDARITY WITH THE WORLD: By joining the trial, we help in the rapid worldwide search for COVID-19 vaccine. You are becoming part of the solution to end the pandemic.

What is an informed consent?

Before a participant agrees to volunteer in a clinical trial, he/she has the right to know and understand what will happen during the course of study. This is called informed consent and it is a process that can help a participant decide whether or not participating in a trial is right for him/her. When the volunteer give written consent to participate in a clinical trial, the volunteer acknowledges that he/she understands and accept all aspects of the research study-including any risks or benefits involved.

Myths	Facts
Participating in the trial will give me immunity to COVID-19.	Joining a clinical trial does not guarantee immunity to COVID-19. Remember that clinical trials are conducted to test the immunogenicity and efficacy of the vaccine under study.
I will earn money by participating in the clinical trials.	Participants of the trial will only receive a minimal allowance to reimburse meals and transportation associated with their participation in the clinical trial. The institutional ethics boards allow such compensation, provided it is not too much as to make monetary considerations the motivation for participating in the trial.
I can participate in multiple clinical trials of different vaccine candidates.	A volunteer can only participate in one clinical trial.
I don't have the right to refuse invitation to participate in clinical trials.	At any time and for any reason, a participant can quit the clinical trial. While participation is very important to the study, it has to be right for the participant. It is always the participant's choice.
The vaccines in clinical trials will treat patients of COVID-19.	The vaccines under study during clinical trials do not promise treatment of COVID-19 patients. Vaccines are not similar to drugs used to treat COVID-19.
Clinical trials are a waste of time and effort.	Clinical trials lead to the discovery of new ways to prevent diseases such as the discovery of vaccine.
Vaccines have no side-effects.	Vaccination may have side effects including pain, redness, itchiness or swelling at the injection site, which may last a few hours. Other side effects may also include fever, feeling of weakness or fatigue, headache, dizziness, diarrhea, and nausea. However, during the trial, the attending physician will determine if the side effects are causally related to the vaccines.

Myths	Facts
It is okay to participate in trials that are not FDA-approved.	No. The participant should check if the clinical trial is FDA-approved.
I must subscribe to any non-expert's opinion about vaccines and trials because they are famous.	No. Get information on clinical trials and vaccines from credible sources.
When clinical trials start, I can go out and socialize with friends without wearing a mask and maintaining social distance	No. A volunteer must still comply with the minimum health and safety standards.
I will have a lifetime immunity against COVID-19 once I get the vaccine.	Immunity induced from administering a vaccine fades over time and the protection differs with each kind of disease and their causative agent Since SARS-CoV-2 is a novel coronavirus, any long term immunity may only be determined once vaccines become available and data on their efficacy of become available after about 6 months from when the phase III trials are completed.
It is okay to participate in trials even without explanations from researchers/doctors.	It is important for a participant to educate himself/herself about the study and its risks and benefits to know if the clinical trial is right for him/her. Make sure the research team is able to answer the questions before joining the trial.

Ethical Implications

Who reviews and approves the trials?

All applications for clinical trials should first be submitted to the sub-TWG for Vaccine Development, reviewed by the Vaccine Expert Panel and by designated Ethics Boards and finally submitted to the Food and Drug Administration for regulatory review and approval for conduct of clinical trials.

What are the rights of the clinical trial participants?

RIGHT TO ASK

The participants may ask and know what the study is trying to find out, why it is being done, what the study will ask the participants to do and who the sponsors and primary / lead investigators are

RIGHT TO FULL DISCLOSURE

Full disclosure and to receive a complete description about the detailed procedure of the research/ study/ clinical trial, including treatment and / or medicines provided/ used in the trial, in a way and language the participants can fully understand.

RIGHT TO BE INFORMED OF THE RISKS

Information about any possible risk, discomfort, and side effects that might happen during and after the research / study/ clinical trial; who to contact when there are questions about the research/ study/ clinical trial and/ or have to report research/ study/ clinical trial related injury, accidents, complications or any adverse effects of treatment, procedures and / or therapy should be available to the participants

RIGHT TO CLEAR INFORMATION

Receive information and clear, understandable explanation about other available procedures, treatment, medication, or treatment / medical options which might be better / less beneficial than those involved in the research / study/ clinical trial as well as their risks and benefits

RIGHT TO DECIDE

Be given enough time to decide whether to participate or not, free from any form of actual or implied force, pressure, or coercion

RIGHT TO REFUSE

To refuse to take part or withdraw any time from the research/ study/ clinical trial, without any effect on the care being received and / or the relationship with the institution, researchers or doctors involved

RIGHT TO KNOW COMPENSATION (If any)

Be informed whether there are any costs associated with the research/ study/ clinical trial, whether the participant will receive payment for participation in the study and who will pay for any research/ study/ clinical trial related injury, accidents, complications or any adverse effects of treatment, procedures and / or therapy

RIGHT TO PRIVACY AND CONFIDENTIALITY

Expect that participant's right to privacy and the confidentiality of participation is safeguarded before, during, and after the study. Be informed about who will have access to information collected and how the confidentiality of this information will be protected.

RIGHT TO BELIEFS

Receive safe and considerate care respectful of the participant's beliefs, religion, and principles

RIGHT TO DOCUMENTS

Receive a duly signed and dated written copy of the consent form of the research/ study/ clinical trial as well as access to the results of the study

RIGHT TO POST-TRIAL CARE

Receive a post-trial care within a reasonable period of time after the trial has ended

RIGHT TO COMPLAIN

Give feedback and/ or complaint. Research participants must report if they experience adverse reactions, untoward events or changes in clinical status while study is ongoing.

How privacy of the participant is protected?

Information about participants in a clinical trial is confidential and can only be accessed by the researchers/doctors who implement the trial. A key aspect of the ethics review process is ensuring that the research team will carry out steps and measures to ensure that participants' information is secure and confidential to the best extent possible.

Who can join the trials?

All potential recipients of the vaccines under the clinical trial will first be screened for certain inclusion and exclusion criteria. These criteria include physical examination, general state of health, and ability to follow instructions among others. Laboratory tests will also be performed such as baseline RT-PCR for SARS-CoV-2 viral RNA, IgM and IgG tests, clinical chemistry examinations to detect abnormalities or disease conditions that may not be detected on physical examination alone.

BASED ON THE RESULTS OF:

- Physical Examination
- State of Health
- COVID-19 Status
- Other Diagnostic Tests

How to enroll for a clinical trial?

For COVID19 vaccine clinical trials, there will be groups who will be prioritized to participate, such as healthcare workers, front-liners, and contacts of COVID19 cases. Participants from the community will be informed about the clinical trial through mass communications with the help of community leaders and health personnel. Orientation meetings and other forms of social media communications may be used, with posters, brochures, etc.

What are the risks?

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However, during the trial, the attending physician will determine if the side effects are causally related to the vaccines. Participants are also given diary cards and are expected to report to the vaccine trial monitor any side effects or development of COVID 19 signs and symptoms during the clinical trial period. Generally, the benefits of taking the vaccine outweigh the risks associated with its side effects.

What can participants get from the trial?

Participants of clinical trials in the Philippines will be given appropriate healthcare services and will be closely monitored by the attending physicians. They will also receive a minimal allowance to reimburse meals and transportation associated with participation in the clinical trial.

III. Contextualizing vaccine clinical trials in the PH setting

WHO Solidarity Trial

The World Health Organization leads the Solidarity Trial for vaccines which aims to harness a global cooperation to develop and evaluate vaccine candidates as quickly as possible (identify vaccine candidates and their progress, define the desired characteristics of safe and effective vaccines to combat the pandemic, and coordinate the clinical trials across the world giving the best chance of safe and effective vaccines for all).

Independent clinical trials

Other vaccine developers, on the other hand, can conduct independent clinical trials in the Philippines provided that they will be able to fund their own trials and register their application with the FDA. Independent trials would have a different sample size based on their requirements for a Phase III Clinical Trial. These will be mainly supervised by the vaccine developers, the contract Research Organization, and/or the medical team to be engaged.

Process of review and approval of clinical trials in the country

All applications for clinical trials should first be submitted to sub-Technical Working Group for Vaccine Development, reviewed by the Vaccine Expert Panel and by designated Ethics Boards and finally submitted to the Food and Drug Administration for regulatory review and approval for conduct of clinical trials.

IV. Clinical Trial Conclusion

What happens when the clinical trials end?

After a clinical trial is completed, the researchers carefully examine information collected during the study before making decisions about the meaning of the findings and about the need for further testing.

Results from clinical trials are often published in peer-reviewed scientific journals. Once a new approach has been proven safe and effective in a clinical trial, it may become a new standard of medical practice.

Economic benefits of vaccination

Vaccination is regarded as one of the most cost-effective health interventions (WHO). Vaccines reduce the risk of people catching a disease making it safer for people to go about their activities, work and travel. Vaccination also helps prevent productivity loss by preventing occurrence of illness and absence from work. Investment in vaccination translates to savings in healthcare, lost wages and productivity lost due to illness and death.

V. What can I do to help?

For Policymakers

- Be updated on latest developments on the vaccine clinical trials in the country.
- Enact policies and laws which are evidence-driven. Consult experts as necessary.
- Avoid sharing fake news and be the authority in sending out correct and credible information to your constituents.

For Community Leaders

- Keep your respective communities informed about the latest on clinical trials.
- Invite experts who can discuss the ongoing initiative of the country on search for vaccine during town hall meetings.
- Maximize the use of social media pages of the localities by posting the materials developed by the country's vaccines communications team.
- Disseminate flyers and information materials in your localities to avoid spread of fake news and protect your constituents from illegal vaccine vendors.

VI. What can I do to help?

For Healthcare Workers

- Get your information straight from the expert by participating in DOH-administered communication trainings.
- Be an active participant in communicating vaccine awareness.

For the General Public

- Avoid sharing fake news about the clinical trials and vaccines.
- Fake news surrounds the online platform, make it a habit to get your information from trusted sources such as the Department of Health and the Department of Science and Technology.

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