Journey towards a COVID-19 vaccine: a cause that unites us all

A Clinical Research Study to Evaluate an Investigational Vaccine for the Prevention of COVID-19 in Adults is Now Enrolling

Information Brochure
What is a Clinical Research Study?

A clinical trial, also called a clinical research study, is a carefully designed scientific evaluation of an investigational vaccine or medication. Prior to participant enrollment, a clinical research study must be reviewed and approved by an institutional review board (IRB)/independent ethics committee (IEC). An IRB/IEC is an ethics committee that may have a mixture of members with regards to their age, gender, race, disability, religion, and sexual orientation. For example, the US Food and Drug Administration (FDA) requires that an IRB have a diverse membership. As a group the IRB/IEC members have the education and experience to review and assess the medical aspects, science, and ethics of a clinical research study.

Clinical research studies are conducted by doctors and researchers, who follow strict rules and procedures to keep participants as safe as possible. Several tests and assessments are performed throughout clinical research studies to monitor participants’ health.

What is an IRB/IEC?

An IRB/IEC consists of 5 or more members. It is made up of doctors, researchers, and non-scientific members; some of the non-scientific members must be people who have never worked as a healthcare professional, clinical researcher, or been involved in the management of clinical research. Only members who are impartial, i.e. are independent of the sponsor of the study and the investigator, can provide opinion or vote on any study-related matters.

IRB/IEC members represent diverse experiences, perspectives, and expertise. They also aim to represent the interests of the local population. The purpose of an IRB/IEC is to protect the rights, safety, and well-being of people taking part in clinical research studies.

The IRB/IEC reviews the study’s documentation to:

- assess whether the study benefits outweigh the study risks
- understand all procedures that will be undertaken to reduce risks
- make sure that participant-facing items, such as the Informed Consent Form, state all the potential risks and benefits in a way that can be easily understood.
Why is clinical research important?

Clinical research helps doctors and scientists determine the safety and efficacy (whether it works) of an investigational vaccine or medication for use in humans to potentially prevent/treat a condition, disease, or disorder. Research has shown that certain diseases and medications may impact people differently based on their age, gender, and genetic background, including race and ethnicity. For example, COVID-19 has disproportionately impacted both older people and minority populations. Therefore, clinical research studies often require large and diverse numbers of volunteers to participate in a single study. Sometimes thousands of volunteers are needed to obtain reliable information. This helps ensure that vaccines and medications are generally safe and work for different types of people, especially those most impacted by the disease or illness.

What is an investigational vaccine?

Vaccines train the body’s immune system to fight against invaders such as viruses and bacteria. In the ENSEMBLE Study, some participants will get an investigational vaccine that aims to prevent COVID-19. The investigational vaccine is still in the testing and evaluation phase and is not licensed for use in the general public.

What is a placebo?

In the ENSEMBLE Study, some participants will get a placebo instead of the investigational vaccine. A placebo looks just like the investigational vaccine and is given the same way, but instead of containing an active vaccine it contains a saline (salt) solution with no active ingredients. Using a placebo in the study will show the potential differences between the investigational vaccine and the placebo.

You cannot contract COVID-19 from the investigational vaccine in this study.
What is Informed Consent?

“Informed Consent” is a process of information exchange before an adult agrees to participate in research. Potential research participants will be asked to read and sign an Informed Consent document. They will also be given instructions, verbally and in writing, question/answer sessions, and other reading materials to assure their understanding and willingness to voluntarily enroll in the research.

So, before you agree to volunteer for the study, the study doctor or staff is required to explain all the details of the study, which will include the risks and benefits, and address your questions.

What is Informed Consent? (continued)

After all of your questions have been answered, and if you wish to participate, then you will sign a document called the Informed Consent Form to ensure:

- You agree to volunteer.
- You understand the study, including the study procedures, risks, and potential side effects of the investigational vaccine or a placebo.
- You understand that you can leave the study at any time, for any reason.

If you don’t understand the document or what is expected of you by participating in the study, you should continue to ask questions and talk with the study doctor. You are also free to discuss the study with your own doctor, your family, your friends, your religious/spiritual leader, or others that you trust, until you feel you understand. Taking part in the study is your decision.
Purpose of the study

The purpose of this clinical research study is to determine the efficacy (whether it works) and safety of an investigational vaccine for the prevention of COVID-19. This investigational vaccine is being evaluated in people 18 years of age or older.

Vaccine clinical research studies can take 10–15 years to complete during normal times. Research and development steps are often completed one after the other, which is why it is a very lengthy process. However, during the current global COVID-19 pandemic there is an urgent need to speed up vaccine research. Clinical research study timelines can be compressed by overlapping some research and development steps. Another way to speed up the process of finding a vaccine that works is to test as many investigational vaccines as possible. For this reason, collaboration during pandemics between vaccine developers and national/international health organizations can be beneficial.

Am I eligible?

You may be able to participate in this study if you:

- are 18 years of age or older
- are in good or stable health (you may have underlying medical conditions if your symptoms and signs are stable and well-controlled)
- have not previously received a vaccine for COVID-19.

Additional eligibility criteria will be assessed by the study doctor or staff during the screening process prior to being enrolled in the study and receiving any investigational vaccine. Not all individuals may qualify to participate in the research.
What can I expect if I join the study?

If you qualify and choose to join the study and sign the Informed Consent Form, you will be asked to attend a screening visit with the study doctor. At this visit, you will undergo tests and procedures to determine if you are a good match for continuing in the study.

- If eligible, you will be in the study for up to 2 years and 1 month and have up to 8 visits (either at home or at the study center) with the study doctor or clinical research staff. If you are diagnosed with COVID-19 while taking part in the study, you will need to collect further information for the study team and may need additional visits.

What can I expect if I join the study? (continued)

- You will be randomly assigned to 1 of 2 groups and will receive 1 injection. Depending on which group you are assigned, you will receive either the investigational vaccine or placebo.
- Neither you nor the study team will know which group you are in.
- The investigational vaccine or placebo will be administered into your arm as an intramuscular injection (a technique used to deliver medication into the muscles; the same as most flu shots).
- Qualified participants will receive study-related medical care and the investigational vaccine or placebo at no cost.
- Qualified participants will also be reimbursed for reasonable trial-related travel expenses to and from study visits. The study will not pay for other medical care or current medication(s) needed to support your daily healthcare routine.

After you complete the study, if you received the placebo, you may be offered the investigational vaccine at no cost. However, this will depend on the results of the study and may not occur until the study is complete.
Can I change my mind?

Yes. You can quit the study at any time, for any reason. Even if you begin the study, you can change your mind at any point.

For more information about this clinical research study, please visit www.ensemblestudy.com or you may contact the site at: