INFORMED CONSENT FORM

A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults Aged 18 Years and Older

Study Name: ENSEMBLE

Study number: VAC31518COV3001

Study Sponsor
Janssen Vaccines & Prevention B.V. (Janssen pharmaceutical company of Johnson & Johnson)

Represented by
[If appropriate, the Local Trial Manager (LTM)/CRO counterpart to insert name of local Sponsor/ Regulatory Sponsor]

[Address of local legal entity]

The Sponsor has partnered with IQVIA to conduct this study.

Study doctor [Insert Investigator name, address, and phone number]

Here are a few key things for you to know:

What is changing:

- The main purpose for this update to the informed consent form is to simplify your study participation.
- Moving forward, participants who are not in a subset (immunogenicity or booster subset) will have only 2 visits remaining on the study, and these will be phone visits where the site staff will call you to ask about your health.
- Participants in the immunogenicity or booster subset will have up to 5 more clinic visits for blood draws.
- You are no longer asked to complete questionnaires about COVID-19 signs/symptoms or to collect nasal swabs and saliva samples if you get COVID.

The following remains unchanged:

- Participation in this research study is voluntary.
- Participation in this research study is not part of your regular health care.
- Our scientific question is *Does the study vaccine protect people from getting COVID-19 illness?*
- Your participation in this study will last for about 2 years.
- Here are some risks with participating:
  - The most common risks are injection site pain, headache, fatigue, muscle pain and nausea after getting the study vaccine.
  - There are other risks. We will tell you more about them later in this consent form.
- There is no guarantee that you will directly benefit from your participation in this clinical study.
- Take your time to decide. You may take an unsigned copy of this form home to re-read and discuss with your doctor/s, family, and friends.
- You may ask the study doctor and site staff any questions.

Current update of Informed Consent includes new/changed/removed information in sections:

- STUDY OVERVIEW
- WHAT HAPPENS DURING THE STUDY?
- WHAT IS DONE AT THE STUDY VISITS?
- STUDY RESPONSIBILITIES
- STUDY VACCINE/OTHER MEDICATIONS
- WHAT ARE THE POSSIBLE SIDE EFFECTS AND RISKS OF PARTICIPATING?
- COMMON QUESTIONS ABOUT JOINING THE STUDY
- BIRTH CONTROL AND PREGNANCY DURING THE STUDY
- HOW IS MY PRIVACY PROTECTED
- YOUR AGREEMENT TO PARTICPATE

Please discuss those updates with your study doctor.

Thank you for taking the time to consider this study.

STUDY OVERVIEW

Why is this study being done?

This study is being done to test the Ad26.COV2.S vaccine. Doctors and scientists hope it will prevent or lessen the severity of disease caused by Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2). This virus causes a disease called COVID-19. The SARS-CoV-2 virus is passed from person to person primarily by small droplets from the nose or mouth when an infected person coughs, sneezes or speaks. Most people who are infected have mild COVID-19 disease such as cough and extreme tiredness, but some people have severe disease and can even die.

The Ad26.COV2.S vaccine, may help to prevent disease by allowing the human body to form an immune response against the virus that causes the disease. This defensive response is a way your body fights infections. This study will help determine if the Ad26.COV2.S vaccine is safe for humans and if it causes an immune response that protects against COVID-19 disease.

The main purposes of this study are to learn

1. If the Ad26.COV2.S vaccine is safe
2. About the side effects caused by the Ad26.COV2.S vaccine
3. If the Ad26.COV2.S vaccine helps to prevent or lessen the severity of COVID-19 illness
4. How long Ad26.COV2.S vaccine is effective against COVID-19 virus

You had an equal chance of receiving either the Ad26.COV2.S vaccine or placebo at the time of entry into the study. Until the Month 6/unblinding visit, neither you nor the study staff knew which vaccine was assigned to each participant. This is called the double-blind phase. At the end of this double-blind phase, you were informed whether you received the vaccine or placebo when you attended your Month 6/unblinding visit (or previously). After unblinding , the study is continuing as an open-label study which means you know whether you received the vaccine.

At the Year 1/Booster visit, you were offered a booster dose of Ad26.COV2.S vaccine. Booster doses will no longer be administered on the study unless there is a medical reason that previously prevented you from receiving the Ad26.COV2.S booster vaccination, or if other COVID-19 vaccines are not available to you.

Throughout this document, when the words “study vaccine” are used, they refer to Ad26.COV2.S vaccine.

General Information about the study

Approximately, 40,000 participants around the world are taking part in this study.

The duration of the study from the time of the randomization visit to the end of the study is about 2 years. We will no longer be collecting saliva samples and nasal swabs. However, some participants (those in a subset) will be asked to continue to provide blood samples.

The study will no longer rely on StudyHub. If you become sick with COVID-19 (and as explained later, **you cannot get COVID-19 from the vaccine**), you no longer have to report signs & symptoms through

StudyHub but you are encouraged to contact the site. In addition, site staff will ask you about COVID-19 episodes during your study visits.

During the study, the Sponsor may learn new information about the study vaccine such as risks. Your study doctor will tell you as soon as possible about any new information that can affect your decision to be in the study. There is a small chance you may have a bad reaction to the vaccine or that the vaccine may make you sicker if you do get COVID-19.

You may choose to not continue participation in this study, in which case you will not lose access to any medical care or other benefits already available to you.

This study is funded by Biomedical Advanced Research and Development Authority (BARDA) and the National Institute of Health, both of which are part of U.S. Department of Health and Human Services.

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WHAT HAPPENS DURING THE STUDY?

The study is divided into 3 parts: 1) Screening Period, 2) Main Study Period and 3) Follow-up Period. You have already completed the Screening Visit 1. Most participants have already completed the Main Study Period and are in the Follow-up Period.

1	2	3
Screening **Visit 1**	**Main Study Period** **Visits 2-6**	**Follow-up Period** **Visits 7-11**
• Screening is the process where it is determined whether you can participate. • Screening happens before you receive the study injection.	• The main Study Period lasts about 1 year and 3 months. • You will receive the study injection at Visit 2 (Day 1). • Some participants will receive an injection at the Month 6/unblinding study visit. • You will be offered a booster dose of Ad26.COV2.S vaccine at Visit 6 (Year 1); this visit will occur as early as 3 months after your last COVID-19 vaccination. • You may have up to 5 clinic visits during this period. • If you develop COVID-19 symptoms, you may contact your site to inform them. You are no longer required to complete the signs and symptoms questionnaires or collect nasal swabs and saliva samples. No further study visits are needed for follow-up on the COVID-19 episode. • Some of the visits might be a telephone call by the study staff. • Unscheduled on-site visits may be required if you experience certain health issues such as thrombocytopenia or a thrombotic event. • If you stop the study early, you will be asked to complete an Early Exit visit.	• At the end of the Main Study Period, your approximate 12-month follow-up period will begin. The purpose of this period is to follow you for safety. • Most participants will have 2 telephone visits (visits 7 - 8) in the follow-up period. • If you are participating in the Immuno Subset and/or a Booster Subset you may have additional clinic visits (visits 7-11). The study staff will inform you if these extra visits apply to you. • If you develop COVID-19 symptoms, you may contact your site to inform them. You are no longer required to complete the signs and symptoms questionnaires or collect nasal swabs and saliva samples. No further study visits are needed for follow-up on the COVID-19 episode. • Unscheduled on-site visits may be required if you experience certain health issues such as thrombocytopenia or a thrombotic event. • If you stop the study early, you will be asked to complete an Early Exit visit.

Some participants will continue to have extra tests and procedures

At the beginning of the study, two small groups of participants were selected for extra tests and procedures: an Immuno Subset and a Safety Subset.

The Immuno Subset is a group of about 400 people with additional blood draws. The reason for this group is so researchers can take a closer look at their immune responses to the study vaccine.

The Safety Subset is a group of up to 6,000 people asked to complete additional diary questions after vaccination. The reason for this group is so researchers have more information about the safety of the vaccine during the 8 days following vaccination.

Two optional, Subsets with additional blood draws were added to the study, starting at the Year 1/Booster visit.

- Booster Subset 1: These participants received 1 dose of Ad26.COV2.S vaccine in the study and received the Ad26.COV2.S booster dose at Year 1. This subset has approximately 200 participants.
- Booster Subset 2: These participants received another authorized or approved COVID-19 vaccine during the study and received the Ad26.COV2.S booster dose at Year 1. This subset has approximately 400 participants.

Approximately 60 participants from each of these 2 Booster Subsets were asked to have 1 extra study visit the day after receiving the booster dose.

The study staff has informed you if you were selected to be included in any of these groups.

In addition, any participant diagnosed with unusual blood clots or a low platelet count may be asked to come to the site to provide additional blood samples for follow-up.

FOR USA PARTICIPANTS ONLY: Real-world data collection introduction

For USA participants only, there is an optional data collection planned for additional medical information to be collected on you to help researchers understand

- if certain medical factors are associated with protection from COVID-19
- if certain medical factors are associated with lack of protection from COVID-19.

You may receive a separate Informed Consent Form with details about this optional sub-study. No action is required from you at this time and by signing this informed consent you are not agreeing to participate in the sub-study.

WHAT IS DONE AT THE STUDY VISITS?

Study procedures and activities

The study has been simplified and the focus will be on following you for safety. For the majority of participants (those not participating in a subset) there are no longer on-site visits; future scheduled visits will be conducted via telephone. On these calls, the study staff will ask you questions about your general health status and COVID-19 episodes. Participants in a subset are asked to continue to attend in-person visits.

The table below explains some procedures that are part of the study.

Procedure	What is it?	When is it done?
Pulse oximetry	Results from the pulse oximetry device will no longer be used for the study.	No longer applicable
Nasal Swab Testing	Nasal samples will no longer be collected and tested for the study. If you test positive for COVID-19, you may share your COVID-19 lab test results with the site staff.	No longer applicable
Saliva Sample Collection	Saliva samples will no longer be collected for the study. If you test positive for COVID-19, you may share your COVID-19 lab test results with the site staff.	No longer applicable
Electronic Device Questionnaires	Electronic device questionnaires are no longer being completed in the study.	No longer applicable
Blood draw/tests	The study doctor or staff will draw blood from a vein in your arm. You may have pain, get a bruise or irritation at the place where the needle goes into your skin. Some participants may faint. In rare cases, the blood draw can cause an infection. Participants that are not part of a subset will have approximately 60 mL – 110 mL (5 – 8 tablespoons) collected during the study. Participants in the Immuno Subset will have approximately 115 mL – 170 mL (about 8 - 12 tablespoons) blood drawn during the study to check for immune responses.	All participants will have blood drawn at Visits 2, 3, 4, 5, and 6. Participants in the Immuno and Booster Subsets will have additional blood

Procedure	What is it?	When is it done?
	Participants in the Booster Subsets will have approximately 130 mL -175 mL (9 – 12 tablespoons) blood drawn during the study to check their immune responses to the booster vaccination. Additionally, about 30 mL (about 2 tablespoons) will be drawn from you in the event of blood clots or low platelets. You may be asked to repeat a blood test if there are safety or technical issues with the initial draw. Your blood will be used to check • For confirmation of SARS-CoV-2 infection • Your immune responses to the study vaccine [Local teams to insert country regulations require a serum pregnancy test]	draws at visits 8, 9, 10, and 11. A selection of participants in the Booster Subsets will have an additional blood draw at Visit 7. Additional blood will be drawn from should you develop blood clots or if you have low platelet counts. Sometimes you may need to repeat a blood test.
Urine sample	If you are a female who could get pregnant, we will collect a urine sample from you to check for pregnancy.	Visits 1, 2 Visit 5 (only participants who received placebo at the beginning of the study and were offered vaccination with Ad26.COV2.S) Visit 6 (only participants that decided to take the booster dose of Ad26.COV2.S)
Sample collection for scientific/genetic research	Any of your blood samples could be used for scientific and limited genetic research as described in the "Samples Collected for Scientific/Genetic Research" section below. You	

Procedure	What is it?	When is it done?
	will be informed if testing on your samples for this study changes.	

Home Health Care (HHC) Language: Do not remove this guidance box from Master ICF.
HHC language is to be included in ICF when studies use a third party home health care provider. This section includes standard HHC language for Global Master Clinical ICF.
<LTM MUST NOTIFY CTM IN THE EVENT OF ANY LOCAL REQUESTED CHANGES TO (INCLUDING REMOVAL OF) THE HHC LANGUAGE>

Home Health Care Visits

Home Health Care Visits are no longer being used for the study.

StudyHub

StudyHub is no longer being used for the study. You can remove the StudyHub application from your phone by following your device's standard procedures for removing applications. If the study staff loaned you a smart phone to access StudyHub you will be asked to return this device as soon as possible.

STUDY RESPONSIBILITIES

To participate in the study, you have responsibilities.

Overall	
Do	**Do not**
• Give correct information about your health history and health condition. • Tell the study staff about any health problems you have during the study. • If you plan to receive the on-study booster talk to your study doctor before getting any other licensed vaccines (such as flu vaccine). • Tell the study staff about any new medicine or drug you take during the study, including over-the-counter drugs (for example, to	• Do not participate in other medical research studies. • Do not get pregnant within 3 months of receiving study vaccination. • Do not donate bone marrow, blood, and blood products from time of the study vaccine administration until 3 months after receiving the study vaccine.

treat side effects after the injection). Also, tell the study staff about any changes to your ongoing medicines or drugs. • Provide all required blood samples. • Attend all study visits and make yourself available for phone calls. • Inform the study staff if you receive a COVID-19 vaccine other than the one provided through this study. • If you receive the Janssen COVID-19 Vaccine and develop any of the symptoms below, immediately contact your clinical research site/healthcare provider and seek medical care. ○ Symptoms of Thrombosis with Thrombocytopenia Syndrome (TTS): severe headache, abdominal pain, leg pain, leg swelling, mental status changes or shortness of breath. ○ Symptoms of Capillary Leak Syndrome (CLS): swelling, low blood pressure, difficulty breathing, weight gain. ○ Symptoms of Guillain-Barré Syndrome (GBS): double vision or difficulty moving eyes, difficulty swallowing, speaking, or chewing, coordination problems and unsteadiness, difficulty walking, tingling sensations in the hands and feet, weakness in the limbs, chest or face, problems with bladder control and bowel function. These conditions are each explained further in this document.	

STUDY VACCINE/OTHER MEDICATIONS

What is the Ad26.COV2.S study vaccine?

The Ad26.COV2.S study vaccine is made from a type of common cold virus called Adenovirus. The adenovirus used to make this vaccine is harmless to people because it has been weakened so it cannot replicate and cause a cold.

The Ad26.COV2.S study vaccine includes genetic material from the SARS-CoV-2 virus. When the study vaccine is injected into your body, the genetic material from SARS-CoV-2 gets "translated" to produce so called 'spike proteins' which are small bits of protein specific to SARS-CoV-2. Our bodies then make an immune response against these spike proteins. This immune response is our body's way of fighting the infection. You cannot get COVID-19 from the study vaccine.

The Ad26.COV2.S vaccine has received emergency use authorization (EUA) by the United States (US) Food and Drug administration (FDA) and conditional marketing authorization by the European Commission. The Ad26.COV2.S vaccine has also been authorized in several other countries/territories worldwide. Your study doctor can inform you of the approval status of the Ad26.COV2.S vaccine in your country.

What injection will I receive?

Booster doses will no longer be administered on the study unless there is a medical reason that previously prevented you from receiving the Ad26.COV2.S booster vaccination, or if other COVID-19 vaccines are not available to you. Your Study Doctor will evaluate if it is safe for you to receive it.

How is the study vaccine given?

The study vaccine is given by injection. The needle is put into the muscle in your upper arm. When possible, the injection will be given in the arm you use less. This was done at Visit 2 (Day 1) and/or the Month 6/unblinding study visit. , and at the time of the Year 1/Booster dose visit.
You will remain at the study site for observation for 15-30 minutes after receiving the vaccine.

What other options are there besides this study?

Do not remove this guidance box from the Master ICF.
ICF Author to add alternative treatments in consultation with SRP/SRS and other study representatives, as applicable. If there are no alternative treatments, this must be stated.
<LTM to modify list based on locally available treatments.>

There may be other vaccines against COVID-19 available in your area, and some COVID-19 vaccines might be recommended for use over other vaccines. [For the US only: For example, the US Centers for Disease Control and Prevention have recommended preferred use of COVID-19 mRNA vaccines over the Janssen vaccine.] The study doctor will explain the benefits and risks of the study vaccine to you and discuss alternative COVID-19 vaccines that may be available to you.

What about my current medicines?

The study staff will ask about all prescription and over-the-counter medicines that you are taking. This includes vitamins and herbs. The study staff will let you know if there are medications you are not allowed to take during the study.

WHAT ARE THE POSSIBLE SIDE EFFECTS AND RISKS OF PARTICIPATING?

Potential Discomforts, Side Effects, and Risks Associated with the Ad26.COV2.S Vaccine

All vaccines can cause side effects. Problems that are not expected may happen and can be life-threatening. If you have any side effects or problems during this study, please tell your study doctor right away.

The possible discomforts, side effects, and risk related to the Ad26.COV2.S vaccine are not all known. Here, we describe the side effects and their frequency in people to whom the Ad26.COV2.S vaccine was given.

Very common side effects with the Ad26.COV2.S vaccine (affecting more than 10% of participants)

- Injection site pain
- Headache
- Fatigue
- Muscle pain
- Nausea

Common side effects with the Ad26.COV2.S vaccine (affecting 1% to 10% of participants)

- Fever
- Reddening of skin at site of injection
- Swelling at injection site
- Chills
- Joint pain

Uncommon side effects with the Ad26.COV2.S vaccine (affecting less than 1% of participants)

- Malaise (generally not feeling well)
- General weakness
- Muscle weakness
- Pain in arm/leg
- Rash

Rare side effects with the Ad26.COV2.S vaccine (affecting 0.1% to 0.01% of participants)

- Allergic reactions
- Hives (urticaria)

Very rare side effects with the Ad26COV2.S vaccine (affecting less than 0.01% of participants)

- Swelling of the lymph nodes (lymphadenopathy)
- Tingling, pricking, burning sensation usually in the hands and feet (paresthesia)
- Numbness in a body part (hypoesthesia)
- Ringing in the ear (tinnitus)
- Diarrhea
- Vomiting
- Guillain-Barré Syndrome

- Thrombosis with Thrombocytopenia Syndrome (TTS)
- Capillary Leak Syndrome (CLS)
- Immune Thrombocytopenia (ITP)
- Severe allergic reactions, including anaphylaxis (see paragraph below)

Allergic reactions, including anaphylaxis

Allergic reactions can occur as dizziness, rapid heartbeat, rash, hives, swelling of lips, mouth, tongue, and in some cases, can cause breathing to become difficult. These reactions may be severe and potentially life-threatening. For example, anaphylaxis is a very rare, life-threatening allergic reaction that may occur soon after vaccination. To monitor for allergic reactions, the study staff will watch you for at least 15 minutes after each injection. Always tell the study staff if you have ever had a bad reaction to an injection or vaccine. They can give you medicines in the clinic to treat allergic reactions. If you think you're having an allergic reaction after you leave the study site, contact the emergency number and get medical help right away. Please inform the study doctor if you have previously experienced anaphylaxis to the Janssen COVID-19 vaccine as you are not allowed to receive the Ad26.COV2.S vaccine in this clinical trial.

Guillain-Barré Syndrome (GBS)

GBS is a rare disorder where the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis. GBS has been reported very rarely following vaccination with the Ad26.COV2.S vaccine. Please seek immediate medical attention and inform the study staff if you experience any of the following symptoms after vaccination with the Ad26.COV2.S vaccine:

- double vision or difficulty moving eyes
- difficulty swallowing, speaking, or chewing
- coordination problems and unsteadiness
- difficulty walking
- tingling sensations in the hands and feet
- weakness in the limbs, chest or face
- problems with bladder control and bowel function.

Thrombosis with Thrombocytopenia Syndrome (TTS)

Blood clots involving blood vessels in the brain, lungs, abdomen, and legs, along with low levels of platelets (blood cells that help your body stop bleeding), have occurred in some people who have received the Ad26.COV2.S vaccine. Some of these cases have been fatal. In people who developed these blood clots and low levels of platelets, symptoms usually began within 3 weeks following vaccination. This condition has been seen in both male and female adults, and was seen most frequently in females aged 50 and younger. TTS following vaccination with Ad26.COV2.S looks very similar to another medical condition called autoimmune heparin induced thrombocytopenia (HIT). Please inform the study doctor if you have previously experienced TTS or HIT as you are not allowed to receive the Ad26.COV2.S vaccine in this clinical trial.

Please seek immediate medical attention if you develop any of the following symptoms after vaccination:

- shortness of breath
- chest pain
- leg pain or swelling
- persistent abdominal pain
- severe or persistent headaches
- blurred vision
- mental status changes or seizures (fits)
- bruising or tiny pinpoint bruises

Capillary Leak Syndrome (CLS)

CLS is a rare illness that causes swelling, low blood pressure, difficulty breathing, weight gain, low protein and sodium in the blood, and can be life threatening. Cases of CLS have been reported following vaccination of the general population with Janssen vaccine. Please inform the study doctor if you have previously experienced CLS as you are not allowed to receive the Ad26.COV2.S vaccine in this clinical trial.

Immune Thrombocytopenia (ITP)

ITP is a disorder that can lead to easy or excessive bruising and bleeding. The bleeding results from unusually low levels of platelets — the cells that help blood clot. "Thrombocytopenia" means low levels of platelets. If you have a history of ITP, please inform the study team who can discuss the risks and benefits of vaccination with you. Very low platelet levels have been reported very rarely outside of the clinical trial setting, usually within the first four weeks after receiving the Janssen COVID-19 vaccine. Please seek immediate medical attention and inform your study doctor if you develop spontaneous bleeding, bruising or tiny pinpoint bruises after vaccination with the Ad26.COV2.S vaccine.

Vaccine enhanced disease (VAED), including vaccine enhanced respiratory disease

Some vaccines may cause a more severe course of illness when you are vaccinated against a disease and then become infected by that disease germ. This is called *vaccine-enhanced disease* (VAED) and it has been described during animal testing for some vaccines against other coronavirus infections such as SARS (Severe Acute Respiratory Syndrome) and MERS (Middle East Respiratory Syndrome). No cases of VAED have been reported following vaccination with the Ad26.COV2.S vaccine. Continuous monitoring for VAED in the clinical studies with this vaccine indicates that the risk of VAED is low.

There may be other risks associated with the Ad26.COV2.S vaccine that we don't know about yet. If we learn new information about the study vaccine and risks associated with it, we will inform you.

Risk of testing positive for SARS-CoV-2 antibodies

After having received the Ad26.COV2.S vaccine, your body may have an immune response to the specific coronavirus proteins that are in the vaccine. This immune response will not affect any results of COVID-19 tests, whether taken as part of the study or outside of the study, that are obtained from

a swab of your nose (or from your throat) as these tests tell you if you currently have COVID-19 virus in your body. Some tests, however, are done to check if you have previously been infected with COVID-19—these tests check for antibodies. These antibody test results might be positive if you received the Ad26.COV2.S vaccine, even if you were never truly infected with the virus.

Other potential risks

Confidentiality:
Because information for this study was obtained using StudyHub on the internet, there is some risk of disclosure of your personal information. All efforts will be made to protect your information, however not all internet connections are secure.

COMMON QUESTIONS ABOUT JOINING THE STUDY

Will I be paid?

Do not remove this guidance box from the Master ICF.
Any statements regarding compensation or reimbursement must be consistent with all study-related documents (e.g., the protocol, CTA, patient recruitment advertising materials or documents submitted by the investigational sites for review and approval). Any applicable company policies (e.g., Healthcare Compliance [HCC] policies) which cover these should be aligned.

You will receive reasonable reimbursement for study related cost (for example, travel/parking costs, meals,).

Who pays for the study vaccine and tests?

Do not remove this guidance box from the Master or Country ICFs.
The following is a requirement per Declaration of Helsinki: A placeholder for information regarding potential conflicts of interest is included in this section to be completed by the site (investigator). Include financial relationships or interests associated with the study e.g., the source of funding and funding arrangements for the conduct and review of the study or information about a financial arrangement or interest of an institution or an investigator such as stock in the Sponsor company or patent on the investigational product. State if the investigator has no financial relationships or interests associated with the study.

There are no costs to you to be in the study. The Sponsor will pay for the study vaccine and the tests that are part of the study.

The Sponsor will not pay for doctor visits, treatments, or tests that are not part of this study.

[LTM/SM TO INCLUDE A STATEMENT ABOUT FINANCIAL ARRANGEMENTS / CONFLICT OF INTEREST OR LACK THEREOF.]

Can the study staff remove me from the study?

Yes, the study staff and the Sponsor have the right to remove you from the study at any time. This decision may occur if

- It is in your best medical interest to do so
- You do not follow the study staff's instructions
- The study is canceled
- You are no longer following the study requirements

The study staff will discuss the reasons for removing you from the study, other treatment or research options, and plans to follow up with you for side effects.

Can I change my mind about participating?

Yes. You can agree to continue in the study now and change your mind at any time and for any reason. Your decision will not change any regular care that you receive from this clinic. Please talk to your study doctor before changing your mind about participation.

What if I get COVID-19 during the study?

Throughout the study you are asked to provide the name of your regular doctor and the hospital you would likely seek care at if you become seriously ill. This is so we can be sure to follow you to check your health. If you get sick with COVID-19 during the follow-up period of the study, you are no longer asked to report signs and symptoms through StudyHub but you may contact the site. In addition, site staff will ask you about COVID-19 episodes during your study visits.

What happens if I stop the study early?

If you stop the study early, the study staff will ask you to do an Early Exit visit. This is to check your health. This information will be added to your study record. If you do not want the study doctor to continue monitoring your health after receiving the study vaccine, you will be asked to indicate this by informing the study doctor. However, it is recommended that you continue to have the study doctor follow you for safety for a period of time.

If the study staff is unable to contact you by conventional means (e.g., clinic/practice visit, telephone, e-mail, fax, or certified mail), he/she may also contact you by reaching out to your emergency contact or by locator agencies and public records, as permitted by local regulations to find out about your health status. By signing this consent form, you agree that this information can be obtained and added to your study record.

If you have side effects from the vaccine or study procedures after you stop the study early, the study doctor or staff may contact your other doctors who you see regularly to get information about your side effects. By signing this consent form, you agree that this information can be obtained and added to your study record.

[LTM TO INCLUDE A STATEMENT OUTLINING MEASURES TAKEN TO IDENTIFY LOSS TO FOLLOW-UP PATIENTS AS ALLOWED PER LOCAL REGULATIONS].

If you stop the study early and withdraw your consent at any time, you agree to allow the use of information collected about you for the purpose of the study up to the point of your consent withdrawal. The Sponsor will continue to collect information from you as described in other sections of this Informed Consent Form (see "Samples Collected for Scientific/Genetic Research," "Samples Used for Future Research," and "What happens if I stop the study early?"). The Sponsor will not collect any new information from you for any parts of the study from which you have withdrawn.

What are the benefits of joining this study?

There is no guarantee that you will directly benefit from your participation in this clinical study. Your participation, however, may help others.

WHAT IF SOMETHING GOES WRONG?

SUBJECT INJURY: Do not remove this guidance box from the Master ICF.
The LTM will complete this section. It must include the country-specific injury language required by local/legal regulations. The text in this section of the site-specific ICF must be consistent with the clinical trial agreement.

BIRTH CONTROL AND PREGNANCY DURING THE STUDY

The effects of the Ad26.COV2.S vaccine in individuals who become pregnant, in unborn, born and breastfed babies are not fully known. There are limited safety data in over 500 reported pregnancies, with over 100 reported pregnancy outcomes with Ad26.COV2.S. These data show that when Ad26.COV2.S is administered within 3 months before pregnancy as well as during pregnancy, no safety concerns to the mother or child have been observed.

Animal studies have been conducted in female rabbits that were given the vaccine prior to mating, early in pregnancy, and again late in pregnancy and then delivered baby rabbits. No adverse effects on reproductive performance, fertility, ovarian and uterine examinations, or the birthing process have been shown.

These same studies have not revealed any effects on male rabbit sex organs that would impair male fertility.

Further, these studies have indicated that antibodies from the mother rabbit were transferred to their fetuses during pregnancy. However, we don't know if this also occurs in humans. So if you become pregnant during or after the study and have antibodies in response to the vaccine, we don't know if the antibodies can be passed to your baby.

If you suspect that you have become pregnant during the study, you must notify your study doctor immediately. The study doctor will collect information about your pregnancy and the health of your baby. If you do not wish to be followed, you can withdraw your consent at any time by informing the study team.

Female Participants Who Can Get Pregnant
If you are an individual who can get pregnant, you must agree to have a urine β-hCG pregnancy test immediately prior to study vaccine administration to record your pregnancy status.

If the result is positive, you may still receive the Ad26.COV2.S vaccine. However, vaccination will depend on local regulations and in consultation with the study doctor and your obstetrician/gynecologist.

Male Participants
If your partner becomes pregnant during the study, you should tell the study doctor immediately. Your partner will be asked for permission to allow the study doctor to follow up and collect information about the pregnancy and the health of the baby. It is entirely voluntary. Your partner does not have to provide any information.

SAMPLES COLLECTED FOR SCIENTIFIC/GENETIC RESEARCH

What happens to the samples collected from me?

The Sponsor may use any of your samples collected during this study to

- Understand how the Ad26.COV2.S vaccine works, or why it may cause side effects
- To better understand COVID-19 disease
- To test if you may be infected with other respiratory viruses such as influenza (flu).
- Understand why people may respond differently to the study vaccine
- To better understand vaccines made from adenoviruses
- To develop tests for Ad26.COV2.S vaccine and SARS-CoV-2 infections.

Researchers may use your samples for genetic testing. Genetic research is the study of DNA and RNA. Differences in genes may explain why some people respond to some medications and others do not. It may also explain why some people get some diseases and others do not.

[LTM TO MODIFY BASED ON LOCAL REQUIREMENTS – ESCALATE TO BIOMARKER REPRESENTATIVE IF THERE ARE CHANGES:] The results of genetic tests done on your samples are only for use in scientific research. They will not be used for your medical care or to make a diagnosis about your health. Therefore, these results will not be given to you or the study staff.

To protect your privacy, your samples will be labelled with the study number and participant number. No personal identifiers are used (such as name, initials, social security number). The scientists doing the research will not know your identity.

Your samples may be sent to the Sponsor and other members of the Johnson & Johnson group of companies and to contractors working for them. Your samples may also be shared with other researchers. Your samples will not be sold or given to any other groups for their use. Researchers working with the Sponsor are not allowed to share samples with anyone who is not authorized by the Sponsor.

You will not be paid for any use of your samples or results, or for inventions made from research on them. You are providing your samples, for use by the Sponsor. The Sponsor (and research partners,

where applicable) will own the use of the results, treatments, or inventions that can be made from this research.

Your collected samples will continue to be analyzed as described in this form unless you specifically ask for your samples to be destroyed. This is to protect the quality of the study.

Samples Used for Future Research
Any samples remaining after they are used for the main study will be stored for future use for up to 15 years or as defined by local regulations. Testing will depend on the available technology at the time of testing. Additionally, your samples could be used for research on future COVID-19 vaccines or other respiratory viral disease vaccines.

You may opt out of future use of your samples or withdraw your consent at any time by notifying your study doctor. If you withdraw consent for future use of your samples, your samples will be destroyed after they are no longer required for the main study. This will not affect your access to the care, medicine, and equipment you would otherwise be getting. This can be done at any time and for any reason. You will need to do this before [#] years since the study doctor/staff will discard the medical records that link your name to your study number in [insert # based on local regulations] years. The Sponsor plans to keep the samples securely in [insert name of [a] facility[ies] in [insert geographical location]. The samples may be relocated at any time by the Sponsor.

HOW IS MY PRIVACY PROTECTED?

Privacy Language: Do not remove this guidance box from Master ICF.
This section includes boilerplate privacy language only for Global Master ICF.
<LTM MUST INSERT THE LEGAL AND PRIVACY WORDING THAT IS THE APPROVED COUNTRY-SPECIFIC TEXT REQUIRED BY LOCAL REGULATIONS **THROUGHOUT** THIS SECTION OF THE ICF. SAMPLE LANGUAGE AND KEY ELEMENTS ARE PROVIDED IN THE COUNTRY ICF LANGUAGE SUMMARY.>
<LTM/SM: THE LANGUAGE IN THE SITE-SPECIFIC ICF MUST BE CONSISTENT WITH THE SPECIFIC CLINICAL TRIAL AGREEMENT.>
NOTE: THE TEXT IN THIS SECTON DOES NOT COVER ALL INFORMATION EXPECTED TO ADDRESS DATA PROTECTION AND PRIVACY. For example:

- The statement that the Clinical Trial will be available on www.clinicaltrials.gov is included in another section of the ICF).
- Information about withdrawal, including the requirement (if applicable) to consult public records to find out the health status of the participant is including in section "What happens if I stop the study early?"

Refer to Job Aid: Escalation of Requested ICF Changes in case of requested changes to privacy language.

The Study Staff and the Sponsor will manage your personal data (information about you) in compliance with [insert reference to applicable law on data protection and privacy] as described in this consent form.

What personal data is collected by the study staff?

The study staff collects and uses your personal data which includes information about your health.

The study staff also collects, records, and uses personal information about you, for study purposes only. Your personal information may include:

- Demographic information such as your name, your study ID #, home address, e-mail address, telephone/mobile number, date of birth, and gender
- Contact information about your emergency contact; and caregiver if applicable
- The name of your regular doctor and the hospital where you would likely seek care if you become seriously ill with COVID-19
- Sensitive information about your physical or mental health or condition
- Information from the questionnaires you are asked to complete

Only the study doctor and the study team will have access to information that can link you to your subject number; this information will not be shared unless necessary for safety purposes.

How will your personal data be protected in StudyHub?

Your previous records in StudyHub will be kept secure.

Your study doctor can provide you with more information about the StudyHub and data collected.

At the time you became a StudyHub user, you were presented the End User License Agreement and Privacy Policy linked to Study Hub, where you reviewed details on the use of the platform and how the data collected is used, handled, and protected.

Home Health Care (HHC) Language: Do not remove this guidance box from Master ICF.
HHC language is to be included in ICF when studies use a third party home health care provider. This section includes standard HHC language for Global Master Clinical ICF.
<LTM MUST NOTIFY CTM IN THE EVENT OF ANY LOCAL REQUESTED CHANGES TO (INCLUDING REMOVAL OF) THE HHC LANGUAGE>

How will your personal data be protected for Home Health Care?

[Vendor name] and their courier will maintain the confidentiality of any personal information and medical data previously collected by storing it in a secure system. Your study staff will have access to this system in order to review the data and for inclusion in your study file.

Who else will have access to your personal data?

Your personal data will be labeled with the study number and your subject number (“Your Coded Data”) before it is reported to the Sponsor. No direct personal identifiers such as your name, initials, date of birth, or social security number are included in Your Coded Data. Your personal data may be stored in paper files and electronic databases which have limited access. The study staff will have

access to them. Other people may also need access to this information to ensure that the research study is being conducted properly, in accordance with laws and ethical requirements.

Monitor(s), auditor(s), independent review board (IRB)/independent ethics committee (IEC), and regulatory authorities *(*including United States Food and Drug Administration) will be granted direct access to your original medical records for verification of clinical study procedures and/or data, without violating your confidentiality, to the extent permitted by the applicable laws and regulations. By signing this informed consent form, you authorize such access.

Records identifying you will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, your identity will remain confidential.

Remote access to your records at the study site

Representatives of the Sponsor (i.e., auditors) may use an electronic tool to access your personal data remotely. This electronic tool provides a secure electronic gateway between the study doctor and staff's computer system and the computer of the representatives of the Sponsor, who may be located outside of your country of residence. This minimizes the risk that anyone else might be able to access the information.

How will Your Coded Data be used by the Sponsor?

Your Coded Data is needed for the Sponsor to learn about Ad26.COV2.S, get permission to introduce and keep it on the market, monitor its safety and get it covered by health insurances and health service providers. Therefore, they will be used as planned in this study as well as within related research activities in order to:

- understand how Ad26.COV2.S works in the body
- better understand COVID-19 and associated health problems
- develop diagnostic tests
- learn from past studies to plan new studies or improve scientific analysis methods
- publish research results in scientific journals or use them for educational purposes.

How will Your Coded Data be shared and transferred by the Sponsor?

The Sponsor may share Your Coded Data with its affiliates, regulatory authorities, authorized service providers and, with select investigators and scientists conducting scientific research, that is compatible with research related to this study including statistical purposes. Your Coded Data may also be shared with scientific journals so the study results can be reviewed by independent scientists and to ensure the accuracy of results. Your identity will not be revealed in any of these cases.
The Sponsor will protect Your Coded Data as far as the law allows and will keep and supervise the information collected about you only for as long as needed.

Sharing of your anonymized data by the Sponsor

Anonymized means your data and samples will be stripped of your participant number as well as of any other information that could identify you. The anonymized data and samples may be shared only for scientific research as allowed by law.

How long will your personal data be stored by the Sponsor?

Records containing your personal data will be retained at the study site for a period of [insert retention period as per local requirements]. In addition, the Sponsor will retain Your Coded Data for time periods as allowed per applicable laws for the identified use.

What rights do you have concerning your personal data?

If you would like to review, correct, delete, or make other requests about your personal data, you should contact your study doctor at [insert contact details].

You may not be able to review some of the data until after the end of the study and a request to delete your personal data cannot be fulfilled where regulations and laws that apply to clinical research require your personal data to be retained.
You can ask your study doctor to send any questions, concerns or complaints you may have to the Sponsor.

HOW DO I LEARN ABOUT THE STUDY RESULTS?

PLS Language: Do not remove this guidance box from Master ICF.

- Plain Language Summary (or "PLS") language is to be included verbatim if study qualifies per EU Clinical Trial Regulation and/or voluntary adoption.

<LTM MUST NOTIFY CTM IN THE EVENT OF ANY LOCAL REQUESTED CHANGES (INCLUDING REMOVAL) TO THE PLS LANGUAGE>

The Sponsor will analyze the data and offer you a summary of the study results after all study participants have completed the study. This may be some time after you have completed your participation in the study. The summary will not include individual results or information that can identify any participants. The summary may be posted on a website or the study staff may be able to give you a written summary.

GENERAL STUDY INFORMATION

Who do I contact for information?

If you have any questions about the study, please contact:
[Insert appropriate study site personnel name, phone number, and title]

If you feel that this study has caused you any harm, please contact:
[Insert Investigator name, phone number, and title]

If you have any questions about your rights as a research participant, please contact the study doctor/staff or:
[Insert IRB or IEC name and phone number]

Study information

Study title: A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults Aged 18 Years and Older
Study number: VAC31518COV3001
Study name: ENSEMBLE

A description of this clinical trial will be available on www.clinicaltrials.gov as required by U.S. law. [LTM to insert other local registries as applicable]. This website will not include information that can identify you. At most, the websitewill include a summary of the study results. You can search this website at any time.
[INCLUDE IF REQUIRED BY LOCAL IRB/IEC:] An independent ethics committee or institutional review board has approved this study.

YOUR AGREEMENT TO PARTICIPATE

If you agree to continue your participation in the study, please read and then sign below.

- I have read and understood this information.
- This study has been explained to me.
- All my questions about the study, the Ad26.COV2.S vaccine, and possible risks and benefits have been answered to my satisfaction.
- I give permission for my personal information to be kept in StudyHub and understand that any data shared and used for the study as explained in this consent form will be Coded Data.
- I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study.
- I understand that I will be given a signed copy of this document to keep.
- If a caregiver is required, I consent to allow my designated caregiver to provide support with my study related activities.

I have been informed that the study doctor/staff may inform my regular doctors (if any) about my participation in this study, and I agree to this. (You may still be in this study even if you do not agree to this.)

Yes ☐ No ☐ Not applicable, I have no other doctors ☐

I give permission for the study staff to inform my designated doctor of any positive SARS-COV2 test results that I may receive as part of my participation in the study.

Yes ☐ No ☐ Not applicable, I have no primary care doctor ☐

I agree to the use of my samples for future scientific research as described in section “Samples Collected

for Scientific/Genetic Research". (You may still be in this study even if you do not agree to this.)

Yes ☐ No ☐

Based on this information, I volunteer to take part in this study.

[NOTE: THE USE OF ELECTRONIC, INCLUDING DIGITAL, SIGNATURES MUST BE IN COMPLIANCE WITH THE APPLICABLE LOCAL REGULATIONS]

Printed name of participant in full

Signature of participant Date (dd/MON/yyyy)

Printed name of person obtaining consent

Signature of person obtaining consent Date (dd/MON/yyyy)

[THE FOLLOWING INVESTIGATOR SIGNATURE MAY BE DELETED, IF NOT APPLICABLE:]

Printed name of investigator if different from the person obtaining consent

Signature of investigator if different from the person obtaining consent Date (dd/MON/yyyy)