INFORMED CONSENT FORM

AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title: **Janssen Vaccines & Prevention B.V./ "A Randomized, Double-blind, Placebo-controlled Phase 1/2a Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of Ad26COVS1 in Adults Aged 18 to 55 Years Inclusive and Adults Aged 65 Years and Older"**

Janssen Research and Development, L.L.C.

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Represented By:

Protocol Number: **VAC31518COV1001**

Principal Investigator: **«PiFullName»**

(Study Doctor)

Telephone: **«IcfPhoneNumber»**

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You are kindly invited to be in a research study.

Here are a few things to know as you learn more:

- Taking part in a research study is voluntary and is not part of your regular health care
- Before you decide, please read this form carefully so you know why the study is being done and what it involves

- Take your time to decide – you may take an unsigned copy of this form home to read again and discuss with your other doctors, family, and friends
- Ask the study doctor or study staff your questions

Thank you for taking the time to consider this study.

Information in this Informed Consent Form may be confidential to the Sponsor. The Sponsor is sharing this information with you for the purpose of inviting you to make an informed decision about participating in the research study. We kindly ask you to consider this sensitive information when discussing details about the research study with people other than your healthcare provider(s), family and friends.

STUDY OVERVIEW

Why is this study being done?

The experimental vaccine in this study is called Ad26COVS1. A vaccine is a type of medicine to prevent certain diseases by causing the human body to form a defensive response against the disease. This defensive response is called the immune response, and it is your body's way to fight infections.

COVID-19, coronavirus disease, is caused by the most recently discovered coronavirus, the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). SARS-CoV-2 is transmitted primarily from person to person through small droplets from the nose or mouth, which are expelled when a person with COVID-19 coughs, sneezes, or speaks. The most common symptoms of COVID-19 are fever, dry cough, and tiredness. Less common symptoms include aches and pains, headache, sore throat, diarrhea, red or irritated eyes, loss of taste or smell, and a rash on skin or discoloration of fingers or toes. Serious symptoms that require immediate medical attention include shortness of breath or difficulty breathing, chest pain or pressure, and loss of speech or movement. Symptoms are usually mild, but some people become seriously ill which can ultimately lead to death. This study will test a new experimental vaccine(s) to help doctors and scientists learn how to prevent COVID-19. The main purpose of this study is to see:

- If the study vaccine(s) is/are safe
- If they cause any side effects
- How well they are tolerated by participants

The study doctors and scientists will also measure:

- How long the effects of the study vaccine(s) last
- How they act on the body
- How the body reacts to the study vaccine(s) (the immune response)

In this study, some participants will get a placebo instead of the study vaccine(s). A placebo looks just like the study vaccine(s) and is given the same way but has no active study vaccine in

it. Using a placebo in the study shows the potential differences between the study vaccine and the placebo (no active study vaccine). The placebo in this study will consist of Sodium Chloride, also known as saline.

Scientists are studying how well Ad26COVS1 works against COVID-19.

All reference to the words “study vaccine” can mean Ad26COVS1 or placebo.

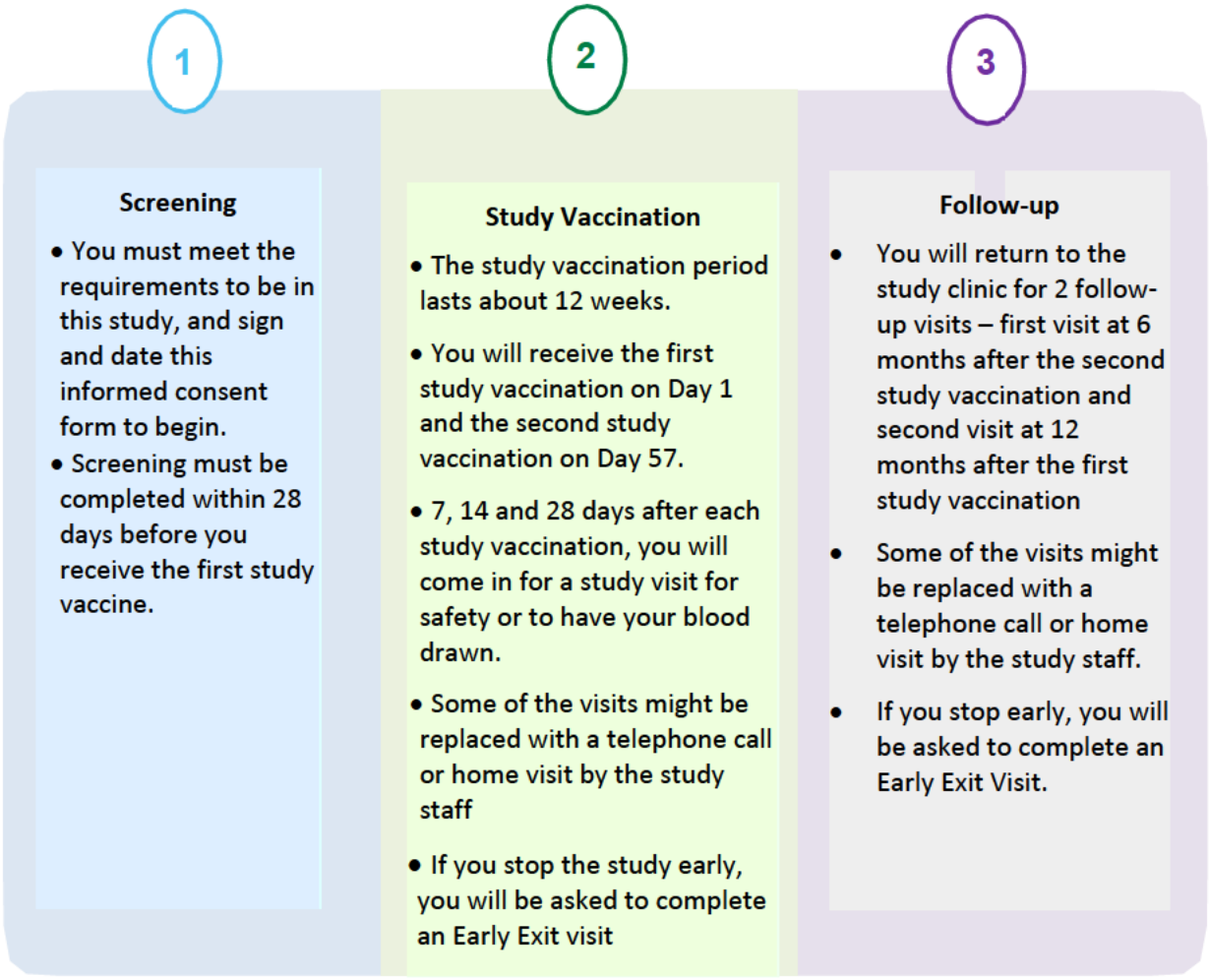
General Information about the study

About 1,045 participants will take part in this study worldwide. If you join the study, you will be in it for about 13 months.

Sometimes during a study, the sponsor may learn new information about the research study vaccine, the risks, or something else. Your doctor or staff will tell you in a timely manner if there is any new information that might make you change your mind about being in the study.

WHAT HAPPENS DURING THE STUDY?

The study is divided into 3 phases.



WHAT IS DONE AT THE STUDY VISITS?

Home Health Care Visits

To help make some study visits more convenient, you may choose to have a medical professional visit you at a preferred location instead of going into the study site. Having a Home Health Care visit is voluntary. You can choose to have a Home Health Care visit or continue to visit your study site for the eligible study visits, shown in the table below. If you choose to have Home Health Care visits for some study visits, you may still need to return to the study site for other visits. This is because there are some visits that are required to be completed at the study site.

Home Health Care visits allow a medical professional (such as a nurse, phlebotomist, or other licensed medical professional) to visit you at a location and time, within the required study visit window, that is convenient for you. This could mean that the visit is performed at your home, place of work, or other location you prefer. We encourage you to select a location that is private and will maintain your confidentiality with respect to your participation in the study.

The table below shows which procedures can be done at home, at the study site, or either.

Study procedures and activities

This table describes all the procedures you can expect to have during the study. Not all procedures will be done at every visit. The study doctor or study staff will discuss this with you in more detail. Please see Schedule of Assessments table at the end of this document, to learn what procedures are done at every visit.

Procedure	**Where is it done?**	What is it?
Informed consent	Site	The study doctor or study staff will talk to you about the study and you'll decide if you want to join.
Review medical history	Site	You will discuss your current and past health with the study doctor or study staff.
Review of medicines	Site	You will talk with the study doctor or study staff about your current medicines.
Physical exam including height and weight	Study Site	The study doctor or study staff will check your body for general health. The study doctor will also take your weight and height.
Vital signs	Study Site or Home	The study doctor or study staff will take your blood pressure, pulse/heart rate, body temperature and respiratory rate (the number of breaths you take per minute).
Blood draw to test for SARS-CoV-2 – specific antibodies	Site or Home	If available, a blood test will be done to identify if you have been exposed to SARS-CoV-2 (the virus that causes COVID-19)

		If the results of your blood test indicate that you have been exposed to SARS-CoV-2, it is possible that you may not be eligible for the study.
Nasal Swab Testing	Site or Home	At the screening visit, a long cotton swab will be inserted in your nose and moved around to collect a sample for testing to see if you have an acute SARS-CoV-2 infection. A nasal swab kit will also be given to you so that a sample can be collected at home if you start to develop COVID-19-like symptoms. It is preferred that the swab is taken by a caregiver (spouse, partner, relative, friend, or health care professional). If that is not possible, you can collect the sample yourself. You will be trained by the study staff and receive paper instructions together with a video on how to use the nasal swab kit.
Review of side effects	Site or Home	At each visit, the study doctor or study staff will ask about any side effects.
Study Vaccination	Site	You will receive the study vaccination from the study staff or study doctor.
Diary	Site	You will be given a paper vaccine diary and an explanation of how to use it. You will report information daily, starting from the day of the study vaccine, and for 7 days afterwards (for a total of 8 daily records). You will do this each time you receive the study vaccine. Study staff will show you how to note: • Daily symptoms, such as tiredness, headache, nausea, and muscle pain • Pain or tenderness, redness, and swelling at the site of the injection (you

		will be provided with a ruler to use at home) • Your daily body temperature using a thermometer (you will be provided with a thermometer to use at home and should measure your temperature at the same time each day) You must bring the diary with you to each visit.
Questionnaires	Site or Home	During the whole study period, you will be asked daily if you experience any COVID-19-like symptoms or not. This is done via the "daily symptom calendar." If the answer is “yes”, you need to contact the study site, complete additional questionnaires on the development of these symptoms, and collect nasal swab samples.
Blood draw/tests	Site or Home	The study doctor or study staff will draw blood from a vein in your arm. You may get a bruise or irritation at the place where the needle goes into your skin. Some participants may faint and, in rare cases, can get an infection. The total amount of blood that will be drawn during the entire study is approximately 244.5 ml (about 1 cup) or, in some selected participants, 737 ml (about 3 cups). In the case of a COVID-19 episode, an additional 17.5 ml (about 1 ¼ tablespoons) per episode would be drawn. Your blood will be used to check for: • Your general health • Confirmation of SARS-CoV-2 infection • How the body reacts to the study vaccine(s) (the immune response)

		The study doctor or study staff will discuss with you the test results that are medically important. Sometimes you may need to repeat a blood test.
Sample collection for scientific/genetic research	Site or Home	A blood sample will be collected for scientific and limited genetic research as described in the "Samples collected for scientific/genetic research" section below. You will be informed if testing on your samples for this study will change.
Review of concomitant medications	Site or Home	You will talk with the study doctor or study staff about any other medications you take including prescriptions medicines, over the counter medications, supplements, vitamins, or herbal products
Phone calls	Home	During the study, the study staff will contact you regularly by telephone or other means of communication to remind you of the procedure to follow in case you are experiencing COVID-19 symptoms. It might also be possible that certain on-site study visits will be replaced by telephone calls or home visits by study staff. Participants that are among the first 5 participants enrolled in the cohort will be called by the study doctor or staff 24 hours after each study vaccination to collect safety information. If this applies to you, your study doctor or study staff will let you know.

Study rules

To participate in the study, you must follow this list of things to do and not do:

Overall study rules	
Do	**Do not**
• Give correct information about your health history and health condition. • Tell the study doctor and study staff about any health problems you have during the study. • Complete the vaccine diary and questionnaires and bring it to all visits. • Come to all study visits. • Agree and be able to be contacted by the study staff on a regular basis.	• Do not take part in any other medical research studies. • Do not get pregnant or cause your partner to become pregnant.
Medicines	
Do	**Do not**
• Tell the study doctor and study staff about any new medicine or drug you take during the study, including over-the-counter drugs (for example, to prevent or treat side effects of the study vaccine). Also tell the study doctor and study staff about any changes to your medicines or drugs.	• Do not get or plan to get any other vaccines (including anti-COVID-19 vaccines) during the study vaccination period unless the study doctor and study staff has approved them beforehand.
Other	
Do	**Do not**
• Bring the "Patient Instructions for Hospitalization" letter with you if you require care at a hospital for any reason	

STUDY VACCINE/OTHER MEDICATIONS

What is the study vaccine?

Ad26COVS1 is a vaccine made from a virus called Adenovirus. This virus is common in everyday life and can cause colds and respiratory infection. However, the adenovirus in this study is harmless to humans. It has been weakened so it cannot cause a respiratory infection.

The study vaccine includes certain parts of the genetic material (DNA) from the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). DNA is a natural substance found in all living things including people, bacteria, and viruses. When the study vaccine is injected in a human, it will tell the body to make small amounts of a protein that SARS-CoV-2 naturally makes. The scientists are looking to see if after getting the study vaccine, a person's body will develop an immune response to the protein of the SARS-CoV-2. An immune response is your body's way to fight infections.

Ad26COVS1 has already been studied in test tubes and in animals. This is the first time that Ad26COVS1 will be used in humans.

What study treatment will I receive?

There are 5 cohorts in this study. Cohorts 1a, 1b, 2a and 2b are for participants 18 through 55 years old. Cohort 3 is for participants 65 years and older. Each study participant will be assigned to one cohort.

You are in Cohort 3.

Within Cohort 3, there are 5 study vaccination groups. Not everyone in the study will get Ad26COVS1. You will either get Ad26COVS1 or placebo. You will randomly (by chance) be put into an active or placebo study vaccine group. The chance that you will get the study vaccine is 300 (80%) out of 375 participants for cohort 3.

During the study, neither you nor the study staff will know which study vaccination group you're in. But if needed for a medical emergency, the study doctor and staff can quickly find out which study vaccine group you're in.

How is the study vaccine given?

If you decide to take part in the study, you also agree to have the study vaccine given as directed by the study staff.

The study vaccine is an injection. The needle is put into the muscle in your upper arm. When possible, the injection will be given in your non-dominant arm (the arm you use the least). You will receive 1ml of the study vaccine two times during the study.

You must remain at the study site for observation for at least 30 minutes after receiving the study vaccine.

What other treatments are there outside of this study?

This study is for research purposes only. Your only alternative is not to participate in this study.

What about my current medicines?

You must tell the study doctor and study staff about all your prescription and over-the-counter medicines. This includes vitamins and herbs.

You can continue to take your regular medication(s) while you are in this study.

WHAT ARE THE POSSIBLE SIDE EFFECTS AND RISKS OF PARTICIPATING?

Risks

Ad26COVS1has been studied in test tube and in animals. In studies where animals were vaccinated with Ad26COVS1 or similar Ad26-based vaccines, no vaccine-related adverse effects were observed.

This is the first time that Ad26COVS1is used in people.

Ad26-based vaccines similar to Ad26COVS1 have been administered to human volunteers in clinical trials designed to prevent RSV (Respiratory Syncytial Virus), HIV (Human Immunodeficiency Virus infections), Ebola/Filovirus, Zika virus, Influenza, Human Papillomavirus and malaria. Overall, Ad26-based vaccines have been administered to more than 67,000 study participants in completed and ongoing trials. In completed clinical trials, a total of 4224 adults and 650 children have received at least 1 study vaccination of an Ad26-based study vaccine up to December 20, 2019.

Side effects previously seen with these vaccine studies include:

- Local symptoms at the injection site
    - Moderate injection site pain
    - Tenderness
    - Moderate to severe redness at the injection site
- Mild to moderate body symptoms
    - Headache
    - Chills
    - Joint pain
    - Muscle pain
    - Tiredness/generally not feeling well/fatigue
    - Nausea
    - Fever

Local and body reactions usually start within 1 to 2 days after study vaccination and most resolve within 1 to 3 days.

A more severe course of the disease caused by vaccines (vaccine-enhanced disease) 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). However, studies in human volunteers with vaccines similar to Ad26COVS1 have stimulated the human immune system to make responses that are very unlikely to cause and may even protect against more severe disease occurring when someone comes in contact with the virus. This was also seen in animal studies with these study vaccines. Nevertheless, the risk of a more severe course of SARS-CoV-2 infection cannot be absolutely ruled out with the vaccine tested in this study. As Ad26COVS1 has not yet been used in people, all study participants will be monitored for possible signs and symptoms of SARS-CoV-2 infection throughout the study. Nasal swab

testing will occur in participants suspected for SARS-CoV-2 infection. Participants with a positive test result will be followed up until resolution of the sign and symptoms, also to ensure appropriate treatment procedures can be initiated to reduce the risk of enhanced disease, should it occur.

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

There may be risks of Ad26COVS1 that we don't know yet. Sometimes during a study, the sponsor may learn new information about the study vaccine and the risks. It is possible that this new information might make you change your mind about being in the study. If new information is discovered, your study doctor will tell you about it right away.

Risks and possible side effects of vaccines in general

All types of injections can cause:

- Stinging, itching, arm discomfort, pain, soreness, redness, hardness, bruising and swelling at the site of injection
- Fever and chills
- Rash
- Itching in other areas of your body
- Aches and pains
- Muscle and joint pain
- Throwing up and nausea
- Headache
- Dizziness
- Feeling very tired

These side effects usually last 48 to 72 hours.

Feeling afraid of an injection might lead to:

- Fainting (can cause someone to fall, but study staff will make sure procedures are in place to avoid falling injuries)
- Fast breathing

Rarely, people may have more severe side effects that limit their normal activities or make them seek medical care. You may take medicines to help with pain and inflammation after the injection, but please report to the study staff if you take these.

Allergic reactions

You could have an allergic reaction to the study vaccine. Some symptoms of allergic reactions are:

- Rash

- Hives
- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat or eyes
- A fast pulse
- Sweating

Some allergic reactions can be life-threatening. The study staff will watch you for at least 30 minutes after each injection.

Always tell the study staff if you have ever had a bad reaction to any injection or vaccine. They can give you medicines in the clinic to treat serious allergic reactions. If you think you're having a severe allergic reaction after you leave the study site, contact the emergency number and get medical help right away.

Side Effects from Tests

- **Blood draw:** Taking blood may cause bruising at the place where the needle goes into the skin. Fainting, and in rare cases, infection, may occur.
- **Collection of nasal swabs**: You may experience some slight discomfort or tickling in the nose while this procedure is being done. It may also cause a nosebleed.

Unforeseen Risks

Since the study vaccine is investigational, there may be other risks that are unknown. Additionally, there may be unknown risks to a pregnancy, embryo, or fetus if you or your female partner become pregnant.

COMMON QUESTIONS ABOUT JOINING THE STUDY

Will I be paid?

«Compensation»

You will be compensated up to $CCI for taking part in this study. Payments will be made as follows:

Visit 1: (Screening-no blood)	$CCI
Visit 2: (Study Vaccine)	$
Visit 4: (No labs)	$
Visit 5: (Labs)	$
Visit 6: (Labs)	$
Visit 7: (Study Vaccine)	$
Visit 9: (No labs)	$

Visit 10: (Labs)	$[redacted]
Visit 11: (Labs)	$
Visit 12: (Labs)	$
Visit 13: (Labs)	$

Completion of your study participation means that you completed all the required study-related procedures at each visit as described in this consent form. If you do not complete the entire study, you will only be compensated for the visit(s) you do complete.

Compensation will be provided on a loadable debit card at the end of each visit and will be accessible to you within 24 – 48 hours after the visit.

If you receive more than $600.00 from the study site in one calendar year, this will be reported to the Internal Revenue Service (IRS) and you will receive a 1099 tax form early in the following year; your Social Security number may be collected for this purpose. You are responsible for paying any state, federal, local or social security taxes.

Who pays for the study vaccine and tests?

The sponsor will pay the institution for the study vaccine and 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. This means that you, your insurance company, or your government health plan may have to pay for these.

The study doctor has no financial relationships or interests associated with the study.

Can the study staff remove me from the study?

Yes, the study doctor or staff and the study sponsor have the right to remove you from the study at any time, with or without your agreement. These decisions will be made if:

- It is in your best medical interest to stop
- You do not follow the study staff's instructions
- The study is canceled
- You no longer meet the eligibility criteria

The study doctor or study staff will discuss with you the reasons for removing you from the study and plans to follow up with you for side effects, if needed.

Can I change my mind about participating?

Yes, you can agree to be in the study now and change your mind at any time and for any reason. You can withdraw from the study and your decision will not change your regular care from your regular doctors.

You can talk to the study doctor or study staff first before making this decision.

What happens if I stop the study early?

If you stop the study early, the study doctor or study staff will conduct an early exit visit with you as soon as possible. This is to make sure that your health is stable. This information will be added to your study record. If you do not want the study doctor to continue monitoring your health after you stop taking Ad26COVS1, you will be asked to indicate this clearly.

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

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

If you stop the study early and withdraw your consent at any time, you agree not to limit 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.

Can I take the study vaccine after the study is over?

After you complete the study, you will no longer receive Ad26COVS1. Your study doctor or staff will discuss your future medical care options with you.

What are the benefits of joining this study?

This study vaccine has not yet been proven effective in preventing COVID-19. There is currently no effective vaccine for the prevention of COVID-19. There is no direct medical benefit to you for participation in this clinical study. Your participation may help future patients.

What about my regular doctors?

The study doctor or study staff may let your regular doctors know that you are in this study and may report any side effects. It is important for your other doctors to know that you may be taking a research study vaccine.

Primary health care provider notification option

I consent to having my family doctor or primary health care provider notified by the study site of my participation in this study and/or any significant findings related to my health (please check yes or no). You may still be in this study even if you do not agree to this.

❒**YES** (If yes, please complete the information below)

❒**NO**

❒**Not applicable (I have no family doctor or primary health care provider)**

Name and address of family doctor or primary health care provider:	Name: Address:
Telephone and Fax Number:	Tel: Fax:

What if something goes wrong?

If you need medical care because of something that happened to you as a result of being in this study, medical care will be provided to you. Janssen Vaccines & Prevention B.V., as the Sponsor of the study, agrees to reimburse the reasonable medical expenses necessary to diagnose and treat an injury caused by the proper administration of the study drug or the proper performance of a procedure required only for the research purposes.

The Sponsor will not pay the costs to diagnose or treat a condition or injury that is not a result of the study drug or procedure, or for expenses related to the normal progression of a preexisting medical condition or an underlying disease. For those costs that are Sponsor's obligation, you or your health insurance won't be billed and in no event will Sponsor pay for coinsurance, copayments or deductibles. It is very important to follow all study directions.

Before or after paying for treatment, Janssen Vaccines & Prevention B.V. or its representatives may need to collect certain personal information about you such as your name, date of birth, gender, social security number, and Medicare identification number (if you have one) in order to comply with a Medicare reporting requirement. This information may be collected directly from you, or from researchers, physicians, or other health care providers who treated your problem or injury. This information and also information about your injury or other health problem may be shared with others, including the Centers for Medicare & Medicaid Services (the federal agency responsible for administering the Medicare program). The above statements do not limit your legal rights.

A new public health declaration, called the Public Readiness and Emergency Preparedness Declaration (PREP), was issued by the Department of Health and Human Services on March 10, 2020. This declaration limits the legal rights of a participant participating in a COVID-19 clinical study that uses a drug, device or vaccine designed to treat, diagnose, cure or prevent COVID-19. This includes the study vaccine Ad26COVS1 used in this study. Participants using Ad26COVS1 in this study will have limits on their right to sue the manufacturers, the study sponsor, healthcare providers and others for significant injuries and adverse reactions.

CAUTIONS

Birth control and pregnancy during the study

The effect of Ad26COVS1 on sperm, egg, conception, pregnancy, an unborn child or a breastfed infant has not been studied. There is currently no information on possible effects of the study vaccine in these cases.

Female Participants Who Cannot Get Pregnant:

If you are postmenopausal for at least two years or have had a total hysterectomy (surgical removal of the womb) or bilateral tubal ligation/clip (surgical sterilization) or surgical removal of both ovaries, you cannot get pregnant (i.e., you are not of child-bearing potential). Therefore, the section below does not apply to you.

Female Participants Who Can Get Pregnant or Are Breastfeeding:

If you are pregnant or breastfeeding, there may be risks to you and your baby that are not known at this time. Therefore, you will not be allowed to take part in the study if you are pregnant or breastfeeding or planning to become pregnant.

If you are female and of childbearing potential (meaning that you are neither post-menopausal for two years nor surgically sterile) and sexually active, you must avoid getting pregnant in order to take part in this study. You will be required to agree to use an approved method of birth control (as described below) beginning 28 days prior to the first study vaccination and continuing until at least 3 months after the last study vaccination. In addition, you will need to have a negative pregnancy test before each study vaccination.

Birth control methods that can be used while in this study include:

- Hormonal contraception
- Intrauterine devices (IUD)
- Intrauterine hormone-releasing systems (IUS)
- Bilateral tubal occlusion/ligation procedure
- Vasectomized partner (the vasectomized partner should be your sole partner)

- Abstinence (defined as refraining from heterosexual intercourse from signing and dating the informed consent until at least 3 months following the last study vaccination)

Please talk to the study staff about specific questions concerning acceptable birth control methods and he/she must approve the method you use before you can enter the study.

If you are a female of childbearing potential, you must agree to have a urine β-hCG pregnancy test at screening and immediately prior to each study vaccine administration to demonstrate that you are not pregnant.

If you suspect that you have become pregnant during the study, you must notify your study doctor immediately. If you become pregnant during the study, you will not receive any further vaccinations. However, you may continue in other study procedures (you may have blood drawn for safety and immune response testing), if the study doctor decides it is safe for you and your unborn child. 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 your study doctor.

Male Participants

If your partner becomes pregnant during the study, you should tell the study doctor immediately. Your partner will be asked to sign and date a separate consent form to allow the study doctor to follow up and collect information about their pregnancy and the health of the baby. It is entirely optional. Your partner does not have to provide any information.

SAMPLES COLLECTED FOR SCIENTIFIC/GENETIC RESEARCH

What happens to the samples collected from me?

Scientific research is done to help improve the development of vaccines and understand the disease better. The sponsor may use any of your samples collected during this study for scientific research to help scientists understand:

- How Ad26COVS1 study vaccine may work, or why they may cause side effects
- To better understand COVID-19
- How to develop tests for Ad26COVS1 study vaccine and SARS-CoV-2 infections.

Scientific research also involves genetic testing. Genetic research is the study of DNA and RNA. DNA carries the information that determines our traits in units called genes. For example, our genes determine the color of our hair and eyes. Genes can be on or off. When a gene is on, it is called ‘active’, and RNA is made. This RNA gives instructions for our bodies to make protein. Proteins are the products made from active genes that do the work in our bodies. For example, a gene determines the color of your hair, but the protein makes your hair a specific color. Differences in genes and how active they are may also 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. Transcriptome analysis is the study of differences in gene activity. It is a blood sample that is mandatory for you to participate in this study.

The results of tests done on these samples are only for scientific research. They will not be used for your medical care. They will not be used to make a diagnosis about your health. Therefore, these results will not be given to you or the study doctor or study staff.

To protect your privacy, your samples will be labeled with your 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 other members of the Johnson & Johnson group of companies, to contractors working for them and to regulatory authorities.

Your samples may also be shared with research partners for scientific research purposes. Your samples will not be sold, loaned or given to any other independent groups for their own use. Research partners working with the sponsor are not allowed to share samples with anyone who is not authorized by the sponsor. The sponsor will manage what is done with your samples.

You will not be paid for any use of your samples, results, or inventions made from research on them. You are providing your samples, for use by the sponsor. The sponsor (and research partners, where applicable) plan(s) to own the use of the results, treatments, or inventions that can be made from this research.

Your collected samples (including blood and nasal swabs) 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

Future Research Testing: Any samples leftover after they are used for the main study will be stored for future use (up to 15 years or defined by local regulations). Testing will depend on the available technology at the time of testing. Additionally, your samples could be used to understand Ad26COVS1, to understand SARS-CoV-2 infection, to understand differential vaccine responders, and to develop tests/assays related to Ad26COVS1 and SARS-CoV-2 infection.

You have the option to opt out of future use of your samples and can withdraw your consent at any time during or after the study 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 15 years since the study doctor or staff will discard the medical records that link your name to your study number in 15 years.

The sponsor plans to keep the samples securely in CSM in Belgium. The samples may be re-located at any time by the sponsor.

HOW IS MY PRIVACY PROTECTED?

The study staff and the sponsor will manage your personal data (information about you) in compliance with the Health Insurance Portability and Accountability Act as described in this consent form.

What personal data will the study staff collect?

If you join this study, the study doctor or study staff will collect and use your personal data to do the research. This personal data may include, among other items, your name, address, date of birth, and health data (information about your health). Health data includes past medical records and data collected during this study, including data collected when analyzing your biological samples as described in "What is Done at the Study Visits?".

Sensitive data, such as racial or ethnic origin will also be collected, as it is necessary for the evaluation of the study results.

Who will have access to your personal data?

Your personal data may be stored in paper files and electronic databases which have limited access. The study doctor or study staff will have access to these paper files and databases. Other people may also need direct 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), IRB/IEC, and regulatory authorities (such as the 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 and dating 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 study are published, your identity will remain confidential.

Remote access to your records at the study site

Representatives of the sponsor (for example, auditors and monitors) may use an electronic tool to access your personal data remotely. This electronic tool provides a secure electronic gateway between the study doctor and study 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 personal data be protected?

Your personal data will be labeled with the study number and your participant 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.

How will your coded data be used?

Your coded data is needed for the sponsor to learn about Ad26COVS1, get it approved for use by regulatory authorities (if the study has positive results), 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 Ad26COVS1 and similar medicines work 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?

The sponsor may share your coded data with its affiliates, regulatory authorities, authorized service providers and, with select investigators and scientists conducting scientific research, which 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. Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Sharing of your anonymized data

The sponsor believes that access to study data advances clinical science and medical knowledge and is in the best interest of public health, provided that the participant's privacy is protected. Therefore, the sponsor may generate and share with some researchers, contractual partners or institutions an anonymized set of your study data. This means your coded data will be stripped of your participant number as well as of any other information that could indirectly identify you, such as your exact height or weight or exact dates of study treatment. This anonymized study data set may be shared only for scientific research as allowed by applicable law.

How long will my personal data be stored?

Records containing your personal data will be retained at the study site for a period of fifteen (15) years . In addition, the Sponsor will retain Your Coded Data for time periods as allowed per applicable laws for the identified use.

What rights do I have concerning my personal data?

If you would like to review, correct, delete personal data, or make other requests concerning your personal data in accordance with the laws in your country, you should contact your study doctor using the information on the first page of this consent form.

Please note that 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 request your study doctor to forward any questions, concerns or complaints you may have to the Sponsor or its representative.

What if I change my mind and do not want my information used or disclosed?

The permission to use or disclose your protected health information for this study does not have an expiration date. In California and any other state which requires an expiration date, the authorization will expire 50 years after you sign and date this form. If you no longer want to share your protected health information, you may cancel your permission at any time by writing to the study staff and/or the Study doctor at the address on the first page of this consent form.

If you cancel your permission after you have started in the study, the study staff and the Study doctor will stop collecting your health information. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study or receive any treatment as part of the study. This is because the study staff and/or the Study doctor would not be able to collect the information needed to evaluate the study [drug] [diagnostic product].

If the study doctor or Sponsor ends your participation, or if you decide not to continue, you will be asked to return to the study doctor or study site to have all of the final clinical evaluations and laboratory tests done.

_____

Printed name of Participant

_____

Signature of Participant Date (MON/dd/yyyy)

Protections for Genetic Information

A Federal law, called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.
- All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009.

Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

GENERAL STUDY INFORMATION

Whom To Contact About This Study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact**:**

- By mail:

  Study Subject Adviser

  Advarra IRB

  6940 Columbia Gateway Drive, Suite 110

  Columbia, MD 21046

- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: PPD.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the study results. You can search this Web site at any time.

YOUR AGREEMENT TO PARTICIPATE

If you consent, please read and then sign and date below.

- I have read and understood this information.
- It has been written in a language that I can read and understand.
- This study has been explained to me.
- All my questions about the study, the study vaccine (Ad26COVS1), and possible risks and side effects have been answered to my satisfaction.
- I give permission for my doctors, other health professionals, hospitals, or labs to release information to the study doctor and study site about my health for the purposes of this study. I understand this information will remain confidential.
- 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 and dated copy of this document to keep.

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

I agree to the use of my blood future scientific research as described in section "Samples Collected for Scientific/Genetic Research," in addition to the testing required for this study.

Check Yes or No:	**Yes**	**No**
	☐	☐

You will receive a copy of this signed and dated Informed Consent Form.

_____

Printed name of participant in full

_____

Signature of participant Date (MON/dd/yyyy)

_____

Printed name of person obtaining consent

_____

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

Impartial Witness Statement

At least one **impartial** witness is mandatory when the participant is unable to read. An **impartial** witness must be present during the entire informed consent discussion.

I confirm that the information in the consent form was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

_____

Printed name of Impartial Witness, in full

_____

Signature of Impartial Witness Date (MON/dd/yyyy)

Visit Number	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**Exit**
Visit Timing	**Screening**	**Vac 1**	**Vac 1 +1d**	**Vac 1 + 7d**	**Vac 1 + 14d**	**Vac 1 + 28d**	**Vac 2**	**Vac 2 +1d**	**Vac 2 + 7d**	**Vac 2 + 14d**	**Vac 2 + 28d**	**Vac 2 +6mo**	**Vac 1 + 12 mo**	
Informed Consent	●													
Medical History, Review of medicines	●	●												
Physical Examination*	●													
Vital signs	●	●		●	●	●	●		●	●	●			●
Blood draw for	●	●												
Nasal swab testing	●	●												
Nasal swab kit training		●												
Study Vaccination		●					●							
Diary Distribution		●					●							
Complete vaccine diary		Vac day +7 days					Vac day + 7 days							
Review of diary			●	●				●	●					
Blood sample		●			●	●	●			●	●	●	●	●
Review side effects and COVID-19-like signs and symptoms (daily)		Continuous												
Review medicines		Continuous												

***Full exam at screening then symptom-directed physical exam at other visits, if necessary**

Phone call from study staff or doctor for first 5 participants enrolled in this cohort 3. If this applies to you, your study doctor or staff will let you know.

VAC = study vaccination; d = day; mo = month; incl = including

Below is a table that shows what happens each day for participants who experience COVID-19-like symptoms

Beginning of signs and symptoms	**Day 1**	**Days 1-4**	**Days 3-8**	**Day 29**	**Until symptoms are resolved**
Contact study site as soon as you have any signs or symptoms of COVID-19	●				
Collect nasal swab at home		●	●		
Physical examination*				●	
Vital signs including body temperature				●	
Blood sample				●	
Take body temperature and record the highest temperature each day		Daily			
Complete questionnaire: Symptoms of Infection with COVID-19 (SIC).		Daily			
Study site staff will contact you	Weekly or more frequently				

***Symptom-directed exam, if necessary**