PARTICIPANT INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION

STUDY TITLE: A Randomized, Double-blind, Phase 3 Study to Evaluate Safety, Reactogenicity, and Immunogenicity of Co-administration of Ad26.COV2.S and Influenza Vaccines in Healthy Adults 18 Years of Age and Older

PROTOCOL NO: VAC31518COV3005

STUDY DOCTOR: <First Name> <Middle Name> <Last Name>, <Suffix>

STUDY SITE: <Company Name>
<Address>
<City, State, ZIP>

TELEPHONE: <Telephone>
<Telephone #2, if applicable>

SPONSOR: Janssen Vaccines & Prevention B.V.

You are 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 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.

KEY INFORMATION

Things you should know:

- The purpose of the study is to test the effects of the investigational vaccine called Ad26.COV2.S when administered in combination with the influenza (flu) vaccine.
- If you choose to participate, you will be asked to attend five study visits and receive three phone calls from study staff. Your participation will last approximately 7 to 8 months.
- Risks or discomforts from this research include vaccination site pain, fatigue, headache, muscle aches and nausea.
- There is no direct benefit to you from participating in this study.

- Your alternatives to participating in this study include receiving a COVID or Influenza vaccine outside of the study.

STUDY OVERVIEW

Why is this study being done?

This study is being done to test the investigational vaccine called Ad26.COV2.S when administered in combination with the influenza (flu) vaccine. Doctors and scientists want to compare the vaccines when administered together and when administered alone.

Doctors and scientists hope the investigational vaccine will prevent or lessen the severity of disease caused by Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2). Doctors and scientists are examining the potential interactions of the Covid vaccine and the flu shot in the adult population. The SARS-CoV-2 virus causes the disease called COVID-19. The SARS-CoV-2 virus passes from person to person primarily by small droplets from the nose or mouth when an infected person coughs, sneezes or speaks. Most healthy people who are infected with coronavirus have mild COVID-19 disease such as cough and tiredness, but some people have severe disease and can even die. Most people who are infected with flu virus have mild respiratory symptoms, but some people have severe disease and can even die.

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.

The main purpose of this study is to find out how well the study vaccine works when participants take it along with an influenza vaccine. Scientists are also studying how safe the study vaccine is when used with the influenza vaccine.

All reference to the words "study vaccine" can mean Ad26.COV2.S and placebo. The placebo looks like the Ad26.COV2.S but does not contain any active ingredients. It is being used in this study so that you do not know which vaccination group you are in.

In this document, you may see the terms "treatment" and "treatment period". These are terms used in research studies and these terms do not mean that you will be receiving medical treatment for any condition. These terms apply to the investigational study drug and parts of the study where you will be receiving this study drug.

General Information about the study

About 1,100 adults age 18 and older will take part in this study worldwide, including about 625 people in the US. If you join the study, you will be participating for about 7-8 months.

Sometimes during a study, the sponsor may learn new information about the research study vaccine, the risks, or something else. Your doctor/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 parts.

1

Screening

- You must meet the requirements to be in this study and sign this informed consent form to begin.
- Screening must be completed within 28 days before you receive the first study vaccine.
- It's possible that the Screening and Day 1 visit can be done on the same day.

2

Vaccination Phase

- The vaccination period lasts about 2 months.
- You will receive the first injections on Day 1 and your second on Day 29.
- Study staff will contact you by telephone 7 days after each vaccination day to assess your safety.
- You will have 1 clinic visit 28 days after the 2nd vaccination.
- During this time, you must complete your symptom diary (7 days post-vaccination) and will receive daily reminders.
- If you decide to stop early, you will be asked to complete an Early Exit Visit where no blood draws will be taken. This visit is intended to assess your safety.

3

Follow-up Phase

- You will get a phone call 90 days after your last vaccination and are required to return to the study clinic 6 months after your last vaccination.
- If you stop early, it is allowed but you will be asked to complete an Early Exit Visit if possible.

WHAT IS DONE AT THE STUDY VISITS?

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.

You can find a full overview per day in the Schedule of Activities at the end of this document.

Procedure	What is it?	When is it done?
Informed consent	The study doctor or staff will talk to you about the study and you'll decide if you want to join.	Screening
Review medical history and medications	You will discuss your current and past health and medicine intake with the study doctor or staff.	Screening
Physical Examination	The study doctor or staff will check your body for general health and will measure your height and weight.	Screening

Vital Signs	The study doctor or staff will take your body temperature, pulse (heart rate), respiratory (breathing) rate and blood pressure.	Screening Visits 2, 3, 4 and 5 Early Exit visit
History of SARS-CoV-2 vaccination	The study doctor or staff will discuss any prior vaccination for SARS-CoV-2 and you are required to provide exact dates of your vaccination history.	Screening
Urine Pregnancy Test	If you are a female who could get pregnant, we will collect a urine sample to check that you are not pregnant before receiving a study vaccine.	Screening Visits 2 and 3
Blood Draw	Qualified study 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. The total amount of blood that will be drawn during the study is 90 mL (about 6 tablespoons). Some rare adverse effects may require special attention. Your doctor will refer to this as an Adverse Event of Special Interest (AESI). If you experience a suspected AESI, additional blood samples (15 mL, about 1 tablespoon) will be collected for safety reasons. AESI are discussed later in the consent under the section "What are the possible side effects and risks of participating?". 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 ▪ Your immune responses to the study vaccine ▪ Your safety and wellbeing	Visits 2, 3, 4 and 5 Early Exit Visit (if applicable)

	The study doctor or staff will discuss with you test results that are medically important.	
Sample collection for scientific research	Blood will be collected for scientific research as described in the "Samples collected for scientific research" section below. You will be informed if testing on your samples for this study will change.	
Vaccination	You will receive the vaccination with the study vaccine as described in the "What treatment will I receive?" in the STUDY VACCINE/OTHER MEDICATIONS section below. The place on your arm where you get the vaccine may have redness and become sore. Please report any post-vaccination reactions in the ediary. Before the vaccination the study doctor or staff will check for any recent infection that causes fever. After the vaccination you will be observed for at least 15 minutes for safety reasons.	Visits 2 and 3
Review of risks and possible side effects of vaccines	At each visit and phone call, the study doctor/staff will ask about any side effects. All vaccines can cause side effects. Problems that are not expected may arise so please communicate any concerns to your site. Potential risks are further outlined below in "What are the Possible Side Effects and Risks?" section.	Throughout the study
Review of Concomitant medication	You will be asked by the study doctor or staff about any other medications you're currently taking including prescription medicines, other vaccines, over the counter medications, supplements, vitamins, or herbal products. You must report to your site any Covid vaccines you may receive during the study (for example, through national	Throughout the study

	vaccination campaigns, community centers, etc.) including mRNA vaccines (Pfizer or Moderna).	
Diary (IQVIA Scribe)	You will be given instructions on how to download and use the IQVIA Scribe app on your own cellular device. If you do not have or would not like to use your own cellular device, then you will be given an electronic diary and provided an explanation on how to use it. You must report information on a daily basis, starting from the day of the study vaccine (in the evening), and for the 7 days afterwards or until symptoms are resolved. You will receive daily reminders on the app to complete the diary. 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 (using a ruler at home) ▪ Your daily body temperature using a thermometer at home (you should measure your temperature orally at the same time each day) You must bring the diary with you to Day 29 visit.	For 7 days after vaccination or until symptoms are resolved.
Diary (IQVIA Scribe) for AESIs	You will have a daily reminder about symptoms that require seeking emergency care and notifying the doctor/site staff.	Beginning with 1st vaccination and for 30 days after 2nd vaccination

IQVIA Scribe

An application (app) called 'IQVIA Scribe' will be used in this study for completing the electronic vaccine diary. If you are unable to answer the questions on the app for any reason, you have the option to contact the site to complete the questions over the phone. The site will be checking to see if you complete the diary every day. The Sponsor partners with IQVIA (a clinical research organization) to use IQVIA Scribe to support this study. You will access IQVIA Scribe using a secure app downloaded to your smart phone. The study staff may be able to provide you with a dedicated smart phone if you do not

have one. To access IQVIA Scribe, you will need to have an account set up, which will be done by the study staff using your email address or phone number.

How will your personal data be protected in IQVIA Scribe?

During account set up, personal data (email address and/or phone number) are used to establish an account. This will be stored in a separate database from the clinical trial data with limited IQVIA staff access. This data will not be used for any other purpose outside of the conduct of this study and will not be accessed by the study sponsor.

When becoming an IQVIA Scribe app user, you will be presented with the End User License Agreement and Privacy Policy linked to IQVIA Scribe, where you can find more details on the use of the platform and how the data collected is used, handled and protected.

Once all your IQVIA Scribe study activities have been completed (maximum first 2 months of study) or you have withdrawn from the study, you can remove the IQVIA Scribe application from your smart phone by following your device's standard procedures for removing applications. You can contact the site staff if you need assistance with this. After all participants have completed the study, IQVIA Scribe for the study will be deactivated.

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 staff about any health problems you have during the study. Note: you should contact the study staff as soon as you start experiencing severe COVID-19-like symptoms. ▪ Complete the diary and bring it to the next visit. ▪ Inform your study doctor of the type of Flu and Covid vaccines received in the past and when (if any). ▪ Talk to your study doctor before getting any other licensed (not live) vaccines (such as tetanus, hepatitis A). ▪ Carry your study participation card with you. ▪ Call your site if you have a fever the day prior your vaccination. ▪ Come to all study visits.	▪ Take part in any other medical research studies (including other COVID-19 vaccine studies) unless they are observational only. ▪ Get pregnant or cause your partner to become pregnant. Do not donate bone marrow, blood, and blood products from the time of the study vaccine administration until 3 months after receiving the study vaccine. ▪ Take pain killers in advance of vaccination to avoid potential discomfort. ▪ Seek blood testing for COVID-19 antibodies (serological test) outside of the study. The vaccine may interfere with the tests and create a false positive result. If you request a serological test, this will be offered at the next scheduled on-site blood draw visit.

Medicines	
Do	**Do not**
▪ Tell the study doctor and 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 staff about any changes to your medicines or drugs.	▪ Get any other vaccines (against flu or Covid) during the study vaccination period without telling your study doctor or study staff.

STUDY VACCINE/OTHER MEDICATIONS

What is the study vaccine?

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

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 US Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for Ad26.COV2.S for the prevention of COVID-19 caused by SARSCoV-2 in adults ≥18 years of age and the European Commission also granted conditional marketing authorization for Ad26.COV2.S.

The seasonal influenza vaccines to be used in this study are called Afluria Quadrivalent for a standard dose and Fluzone HD Quadrivalent for a high-dose.

The high-dose influenza vaccine is approved for use in seniors 65 years of age and older. The standard-dose version is approved for use in people 6 months of age and older. These vaccines are indicated for active immunization for the prevention of seasonal flu.

What treatment will I receive?

Everyone in the study will get Ad26.COV2.S and the influenza vaccine.

There are 4 vaccination groups in this study. You will have a higher chance to be assigned to Groups 3 or 4 if you are older than 65. If you are younger than 65 you will have an equal chance to be assigned to Groups 1 and 2:

- Group 1: Standard Dose of Influenza Vaccine + Ad26.COV2.S on Day 1 and Placebo on Day 29
- Group 2: Standard Dose of Influenza Vaccine + Placebo on Day 1 and Ad26.COV2.S on Day 29
- Group 3 (participants 65 and older): High Dose of Influenza Vaccine + Ad26.COV2.S on Day 1 and Placebo on Day 29
- Group 4 (participants 65 and older): High Dose of Influenza Vaccine + Placebo on Day 1 and Ad26.COV2.S on Day 29

During the study vaccination phase, neither you nor the study staff will know which vaccination group you're in. However, in case of a medical emergency, the study doctor and staff can quickly find out which 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(s) given as directed by the study staff.

The study vaccine is an injection. The needle is put into the muscle in your upper arm. This will be done 3 times during the study. On Day 1, you will receive 2 shots (one in each arm) and on Day 29 you will receive 1 shot.

You must remain at the study site for observation for at least 15 minutes after receiving the study vaccine.

What other vaccines are there outside of this study?

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 example, the US Centers for Disease Control and Prevention have recommended preferred use of COVID-19 mRNA vaccines (Pfizer or Moderna) over the Janssen vaccine.

The study doctor will explain the benefits and risks of the study vaccine with you and discuss alternative COVID-19 vaccines that may be available to you.

What about my current medicines?

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

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

WHAT ARE THE POSSIBLE SIDE EFFECTS AND RISKS OF PARTICIPATING?

<u>Potential Discomforts, Side Effects, and Risks Associated with Ad26.COV2.S</u>

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 risks 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 Ad26.COV2.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 very 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 any 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 Janssen COVID-19 vaccine as you are not allowed to enroll in clinical trials of the Ad26.COV2.S vaccine.

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 three 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 enroll in clinical trials of the Ad26.COV2.S vaccine.

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

These symptoms are considered signs of a suspected Adverse Event of Special Interest (AESI).

If you have a suspected blood clot event or blood clot with low platelets, you may have additional blood collected for testing to determine treatment.

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 the Ad26.COV2.S vaccine. Please inform the study doctor if you have previously experienced CLS, as you are not allowed to enroll in clinical trials of the Ad26.COV2.S vaccine.

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 are not yet known. 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

If you receive the Ad26.COV2.S vaccine, your body may have an immune response to the specific coronavirus protein that is 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.

Risks of Fluzone HD Quadrivalent Vaccine

Like any medicine, the influenza virus vaccine can cause side effects and may not provide protection from disease in every person. You should not receive the influenza virus vaccine if you have a history of severe allergic reactions to any component of the vaccine, including egg protein, or following a previous dose of any influenza vaccine.

Fainting can occur in association with administration of injectable vaccines, including Fluzone® High-Dose Quadrivalent. Procedures will be in place to avoid falling injury and to restoring blood flow to the brain following fainting. In adults who received Fluzone® High-Dose Quadrivalent, the most common

injection site adverse reaction was pain (41.3%); the most common systemic adverse events were muscle aches (22.7%), headache (14.4%), and fatigue (13.2%).

Risks of Afluria Quadrivalent Vaccine

Like any medicine, the influenza virus vaccine can cause side effects and may not provide protection from disease in every person. You should not receive the influenza virus vaccine if you have a history of severe allergic reactions to any component of the vaccine, including egg protein, or following a previous dose of any influenza vaccine.

In adults 18 through 64 years, the most commonly reported injection-site adverse reaction was pain (≥ 40%). The most common systemic adverse events were muscle pain and headache (≥ 20%).

In adults 65 years of age and older, the most commonly reported injection-site adverse reaction was pain (≥ 20%). The most common systemic adverse event was muscle pain (≥ 10%).

[FOR CALIFORNIA, INCLUDE]: The time it takes to recover from the effects of the study vaccine may be 1-3 days, but this cannot be guaranteed.

Other potential risks

Confidentiality

Because information for this study will be obtained using IQVIA Scribe 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.

If you use your mobile device for IQVIA Scribe, it is highly recommended that you set up a passcode on your phone/device to help prevent unauthorized access to your phone and research data.

COMMON QUESTIONS ABOUT JOINING THE STUDY

Will I be paid?

You will not be paid for taking part in this study. You will be reimbursed <Per Visit> per visit for local travel, study visits, and parking.

Who pays for the study vaccine and tests?

There are no costs to you to be in the study.

The sponsor will pay the study doctor and / or the institution, depending on the agreement, for the study vaccines and tests that are part of the study. The sponsor will not pay for doctor visits, treatments, medications, or tests that are not part of this study.

This means that you, your insurance company, or your government health plan are responsible for paying for any medications, treatments, or vaccines (if applicable) that will not be paid for by the sponsor.

[Site Start Specific Language]
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 or patent on the investigational product.

OR

The study doctor has no financial relationships or interests associated with the study.
[End Site Specific Language]

Can the study staff remove me from the study?

Yes, the study doctor/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/staff will discuss with you the reasons for removing you from the study, other treatment or research options, 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 doctors.

Please talk to the study doctor/staff first before making this decision.

What happens if I stop the study early?

If you stop the study early, the study doctor or staff will ask you to come for an Early Exit visit as soon as possible. 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 you stop taking 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 doctor/staff is unable to contact you by conventional means (for example, a 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, 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 unless you indicate otherwise.

If you have side effects after you stop the study early, the study doctor/staff may contact your other doctors who you see regularly. By signing 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 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 trial, you will no longer receive a vaccine. Your study doctor/staff will discuss your future medical care options with you.

What are the benefits of joining this study?

There is no direct medical benefit to you from being in this study. Your participation may provide information that can help prevent other people from getting COVID-19 in the future.

What about my regular doctors?

The study doctor or 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.

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 study's 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.

Birth control and pregnancy during the study

While the cumulative review of pregnancy cases from completed and ongoing clinical studies does not reveal any safety concern related to vaccine exposure during pregnancy, pregnant women will not take part in this study.

Participants of childbearing potential will be required to agree to practicing a highly effective method of birth control and agree to remain on such a method of birth control from the time they consent to enroll until three months after receiving the last study vaccine.

The effects of the Ad26.COV2.S vaccine in individuals who become pregnant and in unborn, born, and breastfed children are yet to be investigated. 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.

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.

If you are an individual who can get pregnant, you must agree to have a urine β-hCG pregnancy test at screening and immediately prior to study vaccine administration to record your pregnancy status.

It is important that women taking part in this study do not become pregnant while taking part in this study and for at least 3 months after receiving the Ad26.COV2.S vaccine.

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.

Female Participants Who Cannot Get Pregnant

If you are postmenopausal for at least one year, have had a hysterectomy (surgical removal of the uterus), surgical removal of both ovaries, or surgical removal of both fallopian tubes, then you are not able to get pregnant. Therefore, the section about required birth control use does not apply to you.

Female Participants Who Can Get Pregnant

If you can get pregnant and are sexually active, consider that there is no data on the effects of the vaccine during pregnancy and the fetus. Therefore, when possible, you should avoid getting pregnant. You will be required to agree to use an approved method of birth control (as described below) beginning at least 28 days prior to the first study vaccination and continuing for 3 months after the administration of last study vaccination.

In addition, you will need to have a negative pregnancy test before each vaccination.

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

- Hormonal birth control
- Intrauterine devices (IUD)
- Intrauterine hormone-releasing systems
- Bilateral tubal occlusion/ligation procedure ("tubes tied")
- Vasectomized partner (the vasectomized partner should be your sole partner)
- Abstinence, if this is your usual and preferred lifestyle choice (defined as refraining from heterosexual intercourse from the time of signing 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.

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 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:

- Understand how Ad26.COV2.S vaccine works when administered in combination with an influenza vaccine and understand why it may cause side effects
- To better understand body responses to Janssen's COVID-19 vaccine
- To better understand vaccines made from adenoviruses and get further insights into their possible interactions with other vaccines

No genetic research will be done on your samples.

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/staff.

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

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.

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/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 at Labcorp in Indianapolis, IN, or at Clinigen in Exton, PA. The samples may be re-located at any time by the sponsor.

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

Your samples may be anonymously 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.

HOW IS MY PRIVACY PROTECTED?

The study staff and the Sponsor will manage your personal data (information about you) in compliance with 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/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?”.

Certain diseases, treatments, and medications may affect people differently based on their age, sex, gender, and genetic background, including race and ethnicity.

Research has shown that there can be significant differences among populations in the way a drug, vaccine or medicine is processed in the body, which may impact its effectiveness (how well it works) and side effects. For this reason, it is important that the people in research studies reflect the population that will use the vaccines, medicines or treatments.

You will be asked certain demographic questions including identifying your race and ethnicity as it is necessary for the evaluation of the study results. This information will also be used to help monitor the participation of different groups of people in the study.

Your response will not affect the care you receive during the study nor will it determine whether you receive the vaccine or placebo.

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/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 FDA (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 (such as auditors, site manager, etc.) 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 personal data be protected?

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.

How will Your Coded Data be used?

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 insurance 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 and other vaccines work in the body;
- better understand the Janssen COVID-19 vaccine's mechanism of action;
- learn from past studies to plan new studies or improve scientific analysis methods;
- share relevant research results with the scientific community and scientific journals for public health interest and educational purposes.

How will Your Coded Data be shared and transferred?

The sponsor may share Your Coded Data with its affiliates, regulatory authorities, such as the FDA (Food and Drug Administration), 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.

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 patients and 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 subject number as well as of any other information that could indirectly identify you such as your exact height or weight or exact dates of 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 15 years. In addition, the sponsor will retain Your Coded Data for time periods as allowed per applicable laws for the identified uses.

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 at <Telephone>.

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. 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 below:

<Company Name>
<Address>
<City, State, ZIP>

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 vaccine.

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.

[FOR CALIFORNIA, INCLUDE]: You have been given a copy of the Research Subject's Bill of Rights and CA HIPAA.

WHAT HAPPENS AFTER THE STUDY?

After all study participants have completed the study (which may be some time after you have completed your participation in the study), the Sponsor will analyze the data and offer you a summary of the study results that are understandable to the general public. The summary will not include individual results or information that can identify you or any other study participant. The summary may be made available to you through a study participant web portal which you can choose to access or through certain local and/or national websites.

At your last visit or after completing the study, you may be contacted by a third party of the sponsor and asked to provide feedback about your participation in the study.

GENERAL STUDY INFORMATION

Who do I contact for information?

If you have questions, concerns or complaints about the research study or you experience a research-related injury, please contact Dr. <Last Name> or the study staff at <Telephone> or <Telephone #2, if applicable>.

If you have questions regarding your rights as a research participant, or if you have questions, concerns, complaints about the research, would like information, or would like to offer input, you may contact the Sterling Institutional Review Board Regulatory Department, 6300 Powers Ferry Road, Suite 600-351, Atlanta, Georgia 30339 (mailing address) at telephone number 1-888-636-1062 (toll free) or info@sterlingirb.com.

Study information

Protocol title: A Randomized, Double-blind, Phase 3 Study to Evaluate Safety, Reactogenicity, and Immunogenicity of Co-administration of Ad26.COV2.S and Influenza Vaccines in Healthy Adults 18 Years of Age and Older

Protocol number: VAC31518COV3005

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 results. You can search this Web site at any time.

YOUR AGREEMENT TO PARTICIPATE

If you consent, please read and then sign 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, 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 <Company Name> / Dr. <Last Name> 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 copy of this document to keep.

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

- I have been informed that the study doctor/staff may inform my other 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.)

Check Yes, No, or Not applicable:

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

- I agree to be contacted by a third party of the sponsor to provide feedback about my participation in the study. My feedback results will be shared anonymously with the sponsor.

Check Yes or No:

Yes ☐ No ☐

- I agree to the use of my samples for future scientific research as described in section “Samples Collected for Scientific Research,” in addition to the testing required for this study.

Check Yes or No:

Yes ☐ No ☐

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

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)

Impartial Witness Statement

At least one **impartial** witness is mandatory when the participant is unable to read or write. 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 (dd/MON/yyyy)

Schedule Of Activities:

Phase	Screening	Treatment Phase					Follow Up		Early termination
Clinic Visit #	1	2	Phone Call	3	Phone Call	4	Phone Call	5	Exit
Visit Day/Week	-28 to 1	Day 1	Day 8	Day 29	Day 36	Day 57	Week 16 (3 mo post Vac 2)	Week 28 (6 mo post Vac 2)	
Informed Consent	●								
Review medical history and medications	●								
Physical examination	●								
Vital signs including body temperature	●	●		●		●		●	●
History of SARS-CoV-2 vaccination	●								
Urine pregnancy test*	●	●		●					
Blood Draw		●		●		●		●	●
Vaccination		●		●					
Review of risks and possible side effects		*Throughout the study*							●
COVID-19 recording		*Throughout the study*							●
Review of Concomitant medications		*Throughout the study*							●
Diary (IQVIA Scribe)		*Throughout the treatment phase*							

*For women of childbearing potential