Title of the study:	**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**
Protocol number:	VAC31518COV1001
Sponsor of the study:	Janssen Vaccines & Prevention B.V., in Belgium represented by Janssen Pharmaceutica N.V., Turnhoutseweg 30, 2340, Beerse, Belgium
Funding organizations:	Janssen Vaccines & Prevention B.V. Biomedical Advanced Research and Development Authority (BARDA)
Research organization:	Centre for the Evaluation of Vaccination – University of Antwerp
Leading Ethics Committee:	Comité d'Ethique Hospitalo-Facultaire Saint-Luc - UCL
Principal investigator:	Professor Pierre Van Damme or a member of his study team Dr. Ilse De Coster Office hours +32 (0)3 265 265 2
Study coordinator:	Leen Suykens Office hours: + 32 (0)3 265 2945
In case of emergency, you can contact the on-call physician on the following telephone number: +32 (0)496 23 07 12.	
The data controller for the personal data at the study site is: Greet Ieven, Greet.ieven@uza.be	

Part I Information vital to your decision to take part

Introduction

Thank you for your participation in this research study so far. We are providing you with this new informed consent form to explain important changes to the study. The study doctor has now informed you that you have received placebo only in this study. As a study participant who only received placebo injections, the following options are now available to you:

- You may choose to receive the sponsor's active vaccine (Ad26.COV2.S) which has received Emergency Use Authorization (EUA) or Conditional Marketing Approval (CMA) as part of the study, **or**
- If you are eligible, you may receive another company's CMA approved COVID-19 vaccine outside of the study which would mean that your participation in the study would be complete, **or**
- You may choose to continue in the study without receiving any CMA COVID-19 vaccine.

You have informed the study doctor that you have chosen to receive the Ad26.COV2.S vaccine as part of the study. The study staff will explain the changes to the study as described in this new informed consent form based on your decision.

You are being invited to continue your participation in the study to evaluate an investigational vaccine, **Ad26COVS1** (JNJ-78436735) (also known as Ad26.COV2.S), in this document also

referred to as a "study vaccine". An investigational vaccine is a vaccine that is still being studied to evaluate its efficacy, safety or mode of action[1].

The sponsor and investigator (also called study doctor) hope that this study vaccine may learn how to prevent COVID-19. 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.

Before you agree to continue your participation in this study, we invite you to take note of its implications in terms of organization, possible risks and benefits, to allow you to make a decision with full awareness of the implications. This is known as giving “informed consent”.

Please read these few pages of information carefully and ask any questions you want to the study doctor or his/her representative. There are 3 parts to this document: the information essential to your decision, your written consent and supplementary information (appendices) detailing certain aspects of the basic information.

If you continue take part in this clinical study, you should be aware that:

- This clinical study is being conducted after having been reviewed by one or more ethics committees.
- Your participation is voluntary and must remain free from any coercion. It requires the signature of a document expressing your consent. Even after having signed this document, you can stop taking part by informing the study doctor at any time. Your decision not to take part or to stop taking part in the study will have no impact on the quality of your care or on your relationship with the study doctor.
- The data collected on this occasion are confidential and your anonymity is guaranteed during publication of the results.
- Insurance has been taken out in case you should suffer any damage in connection with your participation in this clinical study.
- You will not incur any charges for the visits/consultations, examinations or treatments specific to this study.
- You may contact the study doctor or a member of his/her team at any time should you need any additional information.

Further information about your rights as a participant in a clinical study can be found in Annex 2: “Supplementary information on the protection and the rights of the participant in a clinical study”.

[1] Its use in the context of care has not been approved by the regulatory authorities, such as the European Medicines Agency (EMA) and the Food and Drug Administration (FDA) of the United States, or has already been approved by these authorities but for a disease other than that which is the subject of this clinical research. A description and the results of this clinical study will be available via (websites of the EMA https://www.clinicaltrialsregister.eu/; FDA http://www.clinicaltrials.gov/) and published in specialised medical journals.

Objectives and description of the study protocol

The purpose of this study is to see:

- If the study vaccine is safe
- If it causes any side effects
- How well it is tolerated by participants

Another purpose is to measure:

- How long the effects of the study vaccine last
- How it acts on the body
- How the body reacts to the study vaccine (the immune response)

Approximately 1,045 participants are taking part in this study worldwide. Approximately 185 of those participants have received placebo only. At least one Regulatory Authority has now given EUA authorization, Conditional Marketing Approval (CMA), or approval for the Ad26.COV2.S vaccine to be given to people. Since some of the participants in this study were randomly assigned to receive placebo (an injection with no active vaccine), the sponsor has now "unblinded" all participants.

A placebo looks just like the study vaccine and is given the same way but has no active vaccine in it. Using a placebo in the study shows the potential differences between the vaccine and the placebo (no active vaccine). The placebo in this study consists of Sodium Chloride, also known as saline.

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.

"Unblinding" in this context means that the study doctor/staff now know which participants at their site were given Ad26.COV2.S study vaccine injections and which participants at their site were given only placebo.

You have been identified as having received only placebo in this study.

With EUA or CMA in place, you have chosen to receive a single injection containing the 0.5 mL dose of the active Ad26.COV2.S vaccine.

A dose is a measured amount of a vaccine administered at one time.

Any future procedures that were explained as part of your original/previously signed informed consent form(s) will no longer occur. Instead, you will be vaccinated with the 0.5 mL dose of the active Ad26.COV2.S vaccine and asked to remain in the study for 6 months after you receive the active study vaccine.

If your "Day 422 study visit" as referenced in previous informed consent form(s) falls earlier than the end of 6-month follow-up period date, you will remain in the study until your "Day 422 visit" date. This means that the original duration of your participation in the study is not affected by receiving this 0.5 mL dose of the active Ad26.COV2.S vaccine.

More information about procedures related to the post-vaccination follow-up period is outlined in the tables on the next page below.

Course of the study

If you agree to continue your participation in the study, you will first be asked to sign the informed consent form before any study related procedures are conducted.

Your participation in the study will last for approximately 6 months.

Similarly, several additional examinations or procedures will be required in connection with the study (see Table 1 and Table 2 below). Study procedures that have already happened are outlined in the informed consent form you previously signed.

Study procedures that already happened are outlined in the Informed Consent From you previously signed. The tables below provide more detail about the procedures you can expect to have as part of your future study participation if you choose to receive the active study vaccine. Later in this form you will also find a table which shows what happens during each visit.

Table 1: Procedures for placebo participants receiving a single dose of Ad26.COV2.S vaccine after EUA, CMA, or Approval in country

Procedure	**Vaccination Visit**	**End of Follow-up Period** *You will receive a telephone call from the study staff*
Informed reconsent	●	
Urine pregnancy test[a]	●	
Blood sample	●	
Vaccination with active study vaccine	●	
Post-vaccination observation period[b]	●	
Safety reporting[c]	Continuously	
COVID-19 symptoms reporting[d]	Continuously	

a. If you are a female who can get pregnant, you must agree to have a urine β-hCG pregnancy test. A negative pregnancy test is required before receipt of the approved 0.5 mL dose of the active Ad26.COV2.S study vaccine.

b. You will be asked to remain at the study site for 15 minutes after receipt of the active Ad26.COV2.S study vaccine, so that the study staff may observe the presence of any reactions following the vaccination.

c. You will be asked to report any side effects to the study doctor/staff from receipt of the active Ad26.COV2.S study vaccine until the end of the follow-up period/study participation.

d. See Table 2 below for more information.

Table 2: Procedures for participants who experience COVID-19-like symptoms

Beginning of signs and symptoms	**COVID-19 Day 1**	**COVID-19 Days 1-4**	**COVID-19 Days 3-8**	**COVID-19 Day 29**	**Until symptoms are resolved**
Contact study site as soon as you have any signs or symptoms of COVID-19	●				
Collect nasal swab [a]		●	●		
Physical examination [b]				●	
Vital signs including body temperature				●	
Blood sample				●	
Take body temperature and record the highest temperature each day		Daily			

Complete questionnaire: Symptoms of Infection with Coronavirus-19 (SIC)[c]		Daily
Study site staff will contact you	Weekly or more frequently	

a. The nasal swab(s) may be collected at the study site or at home by a health care professional. Your study doctor will discuss your options with you.

b. Symptom-directed physical exam, if necessary.

c. If either nasal swab is positive for COVID-19 or influenza, you will be asked to report information until your symptoms are resolved. If the first nasal swab is negative, you will be asked to report information until the second nasal swab results are negative or until your symptoms are resolved, whichever occurs first.

The study doctor or staff will discuss with you the test results that are medically important.

Study Vaccine

What is the study vaccine?

Ad26.COV2.S 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 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 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.

What treatment will I receive?

Originally, there were 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 through 75 years old. Each study participant has been assigned to one cohort.

As mentioned above, not everyone in the study received Ad26.COV2.S. You were randomly (by chance) put into the placebo vaccine group.

With EUA or CMA in place, and if you choose to sign this informed consent form, you are indicating your choice to receive a single injection containing the 0.5 mL dose of the active Ad26.COV2.S vaccine as directed by the study staff. This is the EUA or CMA approved dose.

How is the study vaccine given?

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). If you decide to receive the study vaccine, you will receive the EUA or CMA approved dose of 0.5 mL of the study vaccine one time during the remainder of your participation in the study.

You must remain at the study site for observation for at least 15 minutes after receiving the vaccine. Prior to your vaccination, a blood sample will be collected. Approximately 7 mL (about ½ a tablespoon) will be collected. If you report certain side effects after you receive study vaccine, the study doctor may collect an additional 30 mL (about 2 tablespoons) of blood.

What other treatments are there outside of this study?

If another vaccine for COVID-19 is authorized or approved for use in your country, you should speak to your study doctor to discuss if and when you are eligible to receive it. There may also

be other clinical studies. The study doctor will explain to you the benefits and risks of these other treatments.

What about my current medicines?

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

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

Risks and discomforts

A: Medicine or other interactions

Some therapies may interfere with the way your body processes the study vaccine and are not allowed during the study. The combination of a study vaccine and a therapy or other vaccine could be harmful to you or could make analysis of your blood samples difficult or impossible. It is very important that you tell the study doctor about all medications or supplements you are taking during the study. Be sure to tell your doctor or study staff immediately about any side effects to avoid possible harm.

Throughout the study (15 months for cohort 1a), the following therapies are not allowed:

- Any investigational medications.
- Any other vaccines (including COVID-19 vaccines) during the study vaccination period unless the study doctor or staff has approved them beforehand.

You must tell the study doctor about all therapies different from the study vaccines you take. This includes prescription or over-the-counter medications, including vaccines, and other kinds of therapy.

B: Side effects of the study medicinal product

The Ad26.COV2.S vaccine has been studied in the test tube and in animals with no vaccine-related adverse effects observed.

Vaccines similar to Ad26.COV2.S (that is, Ad26-based vaccines) have been given to participants in studies designed to prevent RSV (Respiratory Syncytial Virus), HIV (Human Immunodeficiency Virus), Ebola virus, Zika virus, HPV (Human Papillomavirus) and malaria.

As of 22 January 2021, more than 27,181 participants in clinical trials aged 18 and older received at least one dose of Ad26.COV2.S vaccine at the selected dose level of $5x10^{10}$ vp. Of these 27,181 participants, 376 received two doses of Ad26.COV2.S at the selected dose level of $5x10^{10}$ vp.

Following administration of Ad26.COV2.S, headache, fatigue, muscle aches, and nausea appeared to be very common, more so in younger adults (between the ages of 18 and 64 years) than in those aged 65 and older. Nevertheless, taking medication to prevent these symptoms prior to receiving vaccination is not recommended. We recommend that you take a fever reducer or pain reliever if symptoms appear after receiving the vaccination, or upon your study doctor's recommendation. In either case, please tell the study staff if you take anything.

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* 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). However, studies in human volunteers with vaccines

using similar technology to Ad26.COV2.S have produced responses that are not associated with vaccine-enhanced disease. Nevertheless, the risk of a more severe course of SARS-CoV-2 illness cannot be absolutely ruled out with the vaccine tested in this study. Because of this, all participants in this study will be monitored for vaccine- enhanced disease throughout the study. These procedures will allow us to recognize and intervene early in the course of illness. Early recognition and intervention will reduce the risk of a bad outcome if enhanced disease should 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 your participation in this study, you should let your study know doctor right away.

The following side effects have been observed when Ad26.COV2.S vaccine was given to participants:

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

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

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

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

Rare side effects with Ad26.COV2.S vaccine (affecting less than 0.1% of participants)
In a Phase 3 study of the Ad26.COV2.S vaccine, the following rare, serious or important conditions were reported in study participants receiving the Ad26.COV2.S vaccine:

- Blood clot in a deep vein
- Blood clot in the lungs
- Seizures
- Drooping of the face
- Ringing in the ear

Study participants experiencing these rare events may have had underlying medical conditions that placed them at risk for these events. At this time, it is unknown if the vaccine caused these conditions, however, the possibility that the vaccine may have contributed to this event cannot be excluded.

Blood clots involving blood vessels in the brain, lung, 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 one dose of 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 began approximately one to two weeks following vaccination. Most people who developed these blood clots and low levels of platelets were women under 60 years of age. It is not known whether receiving a different dose level or multiple doses of Ad26.COV2.S would change the level of risk or how these events present compared to receiving one dose of the vaccine. Please seek **immediate medical attention** if you develop any of the following symptoms after vaccination: shortness of breath, chest pain, leg pain, leg swelling, persistent abdominal pain, severe or persistent headaches, blurred vision, mental status changes or seizures (fits), easy bruising, tiny blood spots under the skin beyond the site of vaccination.
In the event of a suspected blood clot event or blood clot with low platelets, to facilitate diagnosis and determine treatment options, your study doctor or treating physician may decide about need of additional blood collection.

Several cases of allergic reactions have been reported following the administration of Ad26.COV2.S. These 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. Always tell the study staff if you have ever had a bad reaction to an injection or vaccine. If you think you may be having an allergic reaction, get medical help right away.

There may be other risks associated with Ad26.COV2.S that are not yet known. If new information about the study vaccine and risks associated with it become available, study personnel 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 proteins that are part of 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. For this reason, we recommend that you not seek testing outside of this study, but rather speak with study staff if you need to get tested. The study staff will provide you with additional information and help you get the right test.

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. We do know that antibodies from other vaccines, like tetanus vaccine, do get passed to the baby. For most babies, antibodies passed from the mother last for about six months.

Allergic reactions
You could have an allergic reaction to a vaccine, including a rash, hives, or difficulty breathing. Some allergic reactions can be life-threatening. The study staff will watch you for at least 15 minutes after the active study vaccine 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.

C: Contraception, pregnancy and breast-feeding

Animal studies have shown that Janssen's licensed Ad26-based vaccine against Ebola did not raise concerns in preclinical reproductive toxicity studies. These are studies in pregnant animals that received the vaccine, and then delivered animal babies. Therefore, ongoing studies with the Ebola vaccine allow pregnant women and women planning to become pregnant to receive that vaccine. However, these studies are not yet available for Ad26.COV2.S. The appropriate animal studies are currently underway.

Data on the effects of Ad26.COV2.S on pregnancy in humans, an unborn child and breastfed infants are limited at this time.

Because of the limited data available with this vaccine in pregnant women and women planning to become pregnant, in this study, we will not enroll pregnant women, or women who aim to get pregnant within 3 months of receiving the study vaccine.

Female Participants Who Cannot Get Pregnant

If you:

- are postmenopausal for at least one year **or**
- have had a hysterectomy (surgical removal of the uterus) **or**
- have had surgical removal of both ovaries **or**
- have had surgical removal of both fallopian tubes,

you cannot get pregnant. Therefore, the section about required contraceptive use does not apply to you.

Female Participants Who Can Get Pregnant:

If you can get pregnant and are 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 study vaccination and continuing for 3 months after study vaccination. In addition, you will need to have a negative pregnancy test before the vaccination.

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

- Hormonal contraception
- Intrauterine devices (IUD)
- Intrauterine hormone-releasing systems
- Bilateral tubal occlusion/ligation procedure
- Vasectomized partner (the vasectomized partner should be your sole partner)
- Abstinence (defined as refraining from heterosexual intercourse from signing the informed consent form until at least 3 months following the 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 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 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 doctor.

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 her pregnancy and the health of the baby. It is entirely voluntary. Your partner does not have to provide any information.

D: Risks associated with the evaluation procedures specific to the study

This section is only applicable to the reporting of COVID-19 signs in symptoms as outlined in Table 2 on page 4.

- 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.

Notification of new information

It may be that during the course of a clinical study, important new information on the study vaccine being investigated becomes available. You will be informed of any new element that might affect your decision to continue taking part in this study. It is your choice to continue participation or not.

This updated version of the ICF has been created to explain to you the safety signal in a small number of people who received Ad26.COV2.S vaccine in US and to inform you about restarting vaccinations.

Benefits

As outlined above, you may now choose to receive the EUA or CMA approved 0.5 mL dose of the active Ad26.COV2.S vaccine. Your participation may help future patients.

Withdrawal from the study

Your participation is voluntary, and you are entitled to withdraw from the study for any reason, without having to justify your decision. Nevertheless, it may be useful for the study doctor and for the sponsor of the study to know if you are withdrawing because the constraints of the vaccination are too great (too many uncomfortable side effects, too many post-vaccine procedures for example).

It is also possible that the study doctor or sponsor withdraws you from the study. 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.

Finally, the competent national or international authorities, the ethics committee that initially approved the study or the sponsor may break off the study because the information gathered shows that the study vaccine causes more side effects or more serious side effects than anticipated, or for any other reason, such as, for example, the decision to stop research and development of the study vaccine.

What happens if I stop the study early?

If you stop the study early, the study doctor/staff will conduct a safety follow-up telephone call with you as soon as possible. This is to make sure that you are evaluated for safety measurements before you stop participating in the study.

Information from the follow-up phase is important for continuous monitoring of any side effects that may happen after receiving the study vaccine. This information will be added to your study record. If you do not want to continue with the follow-up phase, you will be asked to indicate this clearly.

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 your study information collected up to the point of the end of study visit. The sponsor will not collect any new information from you for any parts of the study from which you have withdrawn. 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.

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

After you complete the study, you will no longer receive Ad26.COV2.S. Your study doctor or staff will discuss your future medical care options with you.

Samples of biological material collected during the study

The sponsor of the study undertakes that the samples will only be used within the context defined in the section Part I, Section “Objectives and description of the study protocol”.

Since technical progress in this area is constant, if you agree, we would like to retain the surplus of your samples of biological material for 15 years for future research in the context of the present clinical study. This future research can be done to get a better understanding of the study vaccine and the responses to it. Future testing will depend on the available technology at the time of testing. (see in Annex 1 “Supplementary information on the samples collected for scientific research”). Any research outside the context described in this document may only be conducted with the approval of an ethics committee.

If you continue participation in this clinical study, we ask you:

Overall study rules	
Do	**Do not**
• Give correct information about your health history and health condition. • Tell the study doctor or staff about any health problems you have during the study. • Agree and be able to be contacted by the study staff on a regular basis. • Carry the "emergency card" with you at all times. This is imperative for your safety in the event of emergency care in an institution that does not know you.	• 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 or 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 or staff about any changes to your medicines or drugs.	• Do not get or plan to get any other vaccines (including COVID-19 vaccines) during the study vaccination period unless the study doctor or 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	

You should also be aware that:

For your safety, it is advisable for your General Practitioner (GP), if you have one, or other specialists if appropriate to be informed of your participation in this study. We will ask you to confirm your agreement but will respect your wish not to inform them where applicable.

Contact

If you need further information, but also if you have problems or concerns, you can contact the study doctor or a member of his/her research team on the telephone number mentioned on front page.

In case of emergency, you can contact the person mentioned on the front page.

Outside consulting hours, contact the A&E department of your hospital, indicating that you are taking part in a clinical study. Your records will contain information of use to the on-call doctor in relation to this clinical study.

If you have any questions relating to your rights as a participant in a clinical study, you can contact the ethics committee (see the front page for contact details).

Title of the study:	**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**

Part II Informed consent

Participant

I declare that I have been informed of the nature of the study, its purpose, its duration, any risks and benefits and what is expected of me. I have taken note of the information document and the appendices to this document, it is written in a language I can read and understand.

I have had sufficient time to think about it and discuss it with a person of my choice, such as my GP or a member of my family.

I have had the opportunity to ask any questions that came to mind and have obtained a satisfactory response to my questions.

I understand that my participation in this study is voluntary and that I am free to end my participation in this study at any time, without this affecting my relationship with the therapeutic team in charge of my health.

I understand that data about me will be collected throughout my participation in this study and that the study doctor and the sponsor of the study will guarantee the confidentiality of these data.

I agree to my personal data being processed as described in the section dealing with confidentiality guarantees (Annex 2). I also consent to these data being transferred to and processed in countries other than Belgium.

☐ I agree

☐ I do not agree

to the study data collected for the purposes of this study being processed at a later date provided this processing is limited to the context of the present study for a better understanding of vaccines, the disease, its prevention and its treatment.

☐ I agree

☐ I do not agree

to the sponsor retaining samples of biological material collected during the study for up to 15 years for subsequent research purposes but limited to the context of the present study.

☐ I agree

☐ I do not agree

As part of my continued participation in the study, I wish to receive the EUA or CMA approved single-dose Ad26.COV2.S study vaccine and agree to report any side effects to the study doctor/staff for approximately 6 months following receipt of the study vaccination.

☐ I agree

☐ I do not agree

to my general practitioner or other specialists (if appropriate) in charge of my health being informed of my participation in this clinical study.

I have received a copy of the information to the participant and the informed consent form.

_____

First and Last Name of Participant

_____

Signature of Participant Date (dd-MON-yyyy)

Investigator

I, the undersigned, investigator, confirm that I have verbally provided the necessary information about the study and have given the participant a copy of the information document.

I confirm that no pressure was applied to persuade the participant to agree to take part in the study and that I am willing to answer any additional questions if required.

I confirm that I operate in accordance with the ethical principles set out in the latest version of the “Helsinki Declaration”, the “Good Clinical Practices” and the Belgian Law of 7 May 2004 related to experiments on humans.

_____

First name and Surname of the investigator or the investigator’s representative:

_____

Signature of investigator or the investigator’s representative: Date (dd-MON-yyyy)

Title of the study:	**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**

Part III Supplementary information

Annex 1: Supplementary information on the samples collected for scientific research

Samples are any fluid (e.g., blood) or specimen (e.g. nasal swabs) collected from you in this study. Scientific research is done to help improve the development of vaccines and understand the disease better. The sponsor will use the samples collected from you for the purposes of the study and for scientific research.

Your samples may only be used for the following scientific research:

- How Ad26.COV2.S vaccine may work, or why they may cause side effects
- To better understand COVID-19
- How to develop tests for Ad26.COV2.S vaccine and SARS-CoV-2 infections

Different substances in your samples may be tested. 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.

The participation in this genetic part of the study is mandatory. If you do not agree to provide a blood sample for genetic research, you cannot participate in this study.

The results of tests done in these samples, including the blood sample for genetic research, are only for 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 your study doctor/staff.

You will be informed if testing on your samples for this study will change.

Annex 2: Supplementary information on the protection and the rights of the participant in a clinical study

Ethics Committee

This study has been reviewed by an independent Ethics Committee (see front page), which has issued a favorable opinion. It is the task of the Ethics Committees to protect people who take part in a clinical study. They make sure that your rights as a participant in a clinical study are respected, that based on current knowledge the risks to which participants will be exposed have been correctly evaluated and will be reasonably controlled, and that the study is scientifically relevant and ethical. You should not under any circumstances take the favorable opinion of the Ethics Committee as an incentive to take part in this study.

Voluntary participation

Before signing, do not hesitate to ask any questions you feel are appropriate. Take the time to discuss matters with a trusted person if you so wish.

Your participation in the study is voluntary and must remain free of any coercion: this means that you have the right not to take part in the study or to withdraw without giving a reason, even if you previously agreed to take part. Your decision will not affect your relationship with the study doctor or the quality of your future therapeutic care.

However, it is advisable for your safety to inform the study doctor if you have decided to stop taking part in the study.

If you agree to take part, you will sign the informed consent form. The study doctor will also sign this form to confirm that he/she has provided you with the necessary information about the study. You will receive a copy of the form.

Compensation for your participation

The sponsor has arranged to compensate the hospital for the time devoted to the study by the study doctor and his/her team, for the consultations specific to the study and for all examinations scheduled in connection with this study. Similarly, the study vaccine will be paid for by the sponsor.

You will receive a fair reimbursement for your time, travel and possible inconveniences you encounter for taking part in this study.

Payments will be made as follows:

- During the screening period:

  * on site visit = 60 € (it is possible that 2 visits are needed)
- During the study:

  * on site visit = 100 €

  * home visit or telephone visit = 30 €

  * additional fee for long-term study availability and completion of daily questionnaires = 20 €/month
- Reserve subjects (who takes part in all evaluations up to the study vaccination of the selected participants on Day 1 in the morning) will be paid for each screening visit + an additional 170 €
- There will be no separate travel reimbursement.

Contact the site staff for more information and the practical arrangements.

Guarantee of confidentiality

Your participation in the study means that you agree to the study doctor collecting data about you and to the study sponsor using these data for research purposes and in connection with scientific and medical publications.

The study doctor has a duty of confidentiality vis-à-vis the data collected.

This means that he/she undertakes not only never to reveal your name in the context of a publication or conference but also that he/she will encode (your identity will be replaced by an ID code in the study) your data before sending them to the sponsor.

What personal data will the study staff collect[2]?

If you join this study, the study doctor/staff will collect and use your personal data to do the research. The personal data could include your name, address, date of birth, and 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 "Course of the Study".

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

For this study, the legal basis for the processing of your personal data is the regulations and laws that apply to clinical research. This requires the study site to collect and the sponsor to analyze such data before they are submitted to regulatory authorities. In addition, the legal basis can be the performance of the scientific research that is referenced in this consent form.

The data controller for the personal data at the study site is mentioned on the first page. The data protection officer of the study site is also at your disposal. You will find his / her contact details on page 1. The sponsor (see page 1) is responsible for the processing of the data.

Who will have access to your personal data?

Your personal data may be stored in limited-access paper files and databases. 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), the independent ethics committee, and regulatory authorities 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.

Each of these individuals will be obligated to protect the confidentiality of your personal data and to use and disclose it only as described in this document.

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

[2] In accordance with the Belgian law of 30 July 2018, the Belgian law of 22 August 2002 and the Regulation (EU) 2016/679 of 27 April 2016 which entered into force on 25 May 2018, your privacy will be respected concerning the protection of natural persons in connection with the processing of personal data and on the free movement of these data.

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 personal identifiers such as name, initials, date of birth or social security number are included in Your Coded Data.

The data controller for Your Coded Data is the sponsor of the study (see page 1 for contact details).

How will Your Coded Data be used?

Your coded data is needed for the sponsor to learn more about Ad26.COV2.S, 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 Ad26.COV2.S 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 as well as with business partners with whom it is working to jointly conduct scientific research in other countries. The data protection laws in these countries may be less protective than data protection laws in the European Economic Area (EEA). With regards to transfers from the EEA to other countries, including the United States., the sponsor has put in place adequate measures to protect your information and to permit the compliant cross-border transfer of Your Coded Data. You may contact your Study Doctor to request a copy of these measures.

How long time will my personal data be stored?

Records containing your personal data will be retained at the study site for a period of at least 25 years after the end of the research study. In addition, the sponsor will retain Your Coded Data for period as allowed per applicable laws for the identified use (25 years).

What rights do I have concerning my personal data?

If you would like to review, correct, update, restrict, object to the processing or delete personal data, or if you would like to receive an electronic copy of the personal data you have provided, you should contact your study doctor. 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 in case regulations and laws that apply to clinical research require your personal data to be retained.

The person responsible for processing the personal data may, if required, provide you with more information about the protection of your personal data. See page 1 for contact details of the person responsible for processing the personal details of this study site.

You can request your study doctor that any questions, concerns or complaints you may have is forwarded to the data protection officer of the sponsor or its representative (e-mail: emeaprivacy@its.jnj.com).

You have the right to lodge a complaint about how your information is handled, with the Belgian supervisory authority responsible for enforcing the data protection legislation: Data Protection Authority (DPA), Drukpersstraat 35, 1000 Brussels, Tel. +32 2 274 48 00, e-mail: contact@apd-gba.be.

Website: www.dataprotectionauthority.be

Future of your sample(s) collected during the study

The sample encoding procedure is the same as that used for your medical data. Samples sent to the sponsor will therefore only include your study ID code.

The manager of these samples (Janssen Biobank, Turnhoutseweg 30, 2340 Beerse) undertakes to use them within the context of clinical research and to destroy them at the end of the scheduled storage period.

Your samples may be sent to other members of the sponsor (part of 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.

The sample of biological material taken is deemed to be a “donation” and you should be aware that, in principle, you will not receive any financial benefit (royalties) associated with the development of new therapies derived from the use of your donation of biological material and which may be of commercial value.

If you withdraw your consent to take part in the study, you may contact the study doctor and have those of your samples that have not yet been used destroyed. The results obtained from your samples before you withdraw your consent remain the property of the study sponsor.

Insurance

Any participation in a clinical study involves a risk, however small it is. Even if there is no fault, the sponsor accepts responsibility for damage caused to the participant (or in the event of death, his/her dependents) and directly or indirectly linked to his/her participation in the study. The sponsor has taken out insurance for this responsibility[3].

You are therefore asked to report any new health problem to the study doctor. He/she will be able to provide you with additional information concerning possible treatments.

If the study doctor believes that a link with the study is possible, he/she will inform the study sponsor, which will initiate the declaration procedure to the insurance company. The latter will appoint an expert - if it considers it necessary - to assess whether there is a link between your new health problems and the study.

In the event of disagreement either with the study doctor or with the expert appointed by the insurance company and also whenever you feel it is appropriate, you or - in case of death - your dependents may bring proceedings against the insurer directly in Belgium (BECANA03390 issued by Chubb European Group SE, Terhulpsesteenweg 166 at 1170 Brussels and in the name of J.C. General Services CVBA, Turnhoutseweg 30, 2340 Beerse).

The law provides that the insurer may be summoned to appear either before the judge of the location where the event giving rise to the damage occurred, or before the judge of your domicile, or before the judge of the insurer’s registered offices.

[3] In accordance with Article 29 of the Belgian Law related to experiments on humans (7 May 2004)