PATIENT INFORMATION SHEET AND INFORMED CONSENT FORM

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

EU number: 2020-003643-29

Trial number: VAC31518COV3009

Sponsor(s) of the trial: Janssen Vaccines & Prevention B.V. (Janssen pharmaceutical company of Johnson & Johnson) Archimedesweg 4, 2333CN, Leiden, The Netherlands

Contract Research organisation: IQVIA RDS & Integrated Services Belgium NV/SA, Corporate Village, Davos Building, Da Vincilaan 7, 1930 Zaventem, Belgium

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Document Revision History

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V5.0BEL(en)1.0	11Jan2021	Updated based on protocol amendment 3 and updated of the master ICF.

Who can I contact in case of questions?

Name	**Function**	**In case of**	**Contact details**
Dr. Patrick Soentjens	Principal Investigator of the site	Information, problems or concerns	+32 498 76 80 19, psoentjens@itg.be
	The trial staff	Information, problems, concerns	+32 3 34.55.670 (+32 460 85 01 15)
	Emergency contact	Emergency	+32 3 34 55 672
	Patient rights ombudsman	Concerns relating to your rights as a participant in a trial	+32 3 34 55 671
Chubb European Group SE Terhulpsesteenweg 166, 1170 Brussels, Belgium	Insurance Company of the sponsor	In case of disagreement or complaint on a damage claim	BECANA03390
	Data protection officer of the **site**	Questions relating to the confidentiality of your data	E-mail: jverellen@itg.be
	Belgian Data Protection Authority	Complaints relating to the confidentiality of your data	E-mail : contact@apd-gba.be

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THE TRIAL AT A GLANCE

Information in this Informed Consent Form may be confidential to the Sponsor. The Sponsor is sharing this information with you so you will know details about the trial as you decide whether to participate in the study. We ask you to consider this private information when discussing details about the research study with people other than your healthcare provider(s), family and friends.

You are being asked to take part in a clinical trial. This trial is being done to test the new experimental vaccine called Ad26.COV2.S. Doctors and scientists hope it will prevent or lessen the severity of disease caused by Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2). This virus causes a disease called COVID-19. The scientific question of the trial is: Does the trial vaccine protect people from getting COVID-19 illness?

It is possible you will not benefit from participating in this trial because we do not know if the vaccine works to prevent COVID-19 disease. Your participation, however, may help future vaccine recipients.

Joining this clinical trial is voluntary. It is your choice to participate or not. Take your time to decide – You may take an unsigned copy of this form home to re-read and discuss with your treating physician, family, and friends. You may ask the investigator and site staff any questions

If you join, your participation in this trial will last for about 2 years and 3 months.

All participants will receive 2 injections, approximately 2 months apart. Some participants will receive 2 injections of Ad26.COV2.S vaccine and others will receive 2 injections of placebo. The placebo looks just like the Ad26.COV2.S vaccine and is given in the same way, by injection (shot). But the placebo contains no active vaccine. The placebo in this trial will be sodium chloride, also known as sterile saltwater. Throughout this document, when the words “trial vaccine” are used, they refer to either the Ad26.COV2.S vaccine or placebo.

During the trial, you will have blood draws, saliva samples and swabs of your nose taken, and you will answer questions (in an electronic system) on how you are feeling.

Here are some risks with participating:

The most common risks are symptoms such as muscle aches, headaches, or fever after getting the trial vaccine or placebo. There is a small chance you may have a bad reaction to the vaccine or that the vaccine may make you sicker if you do get COVID-19.

The following trial procedures can also involve risk: vaccine administration, nasal swab testing and blood draw. We will tell you more about them later in this consent form.

The sponsor of this trial, the company Janssen, has taken out insurance for this trial. A copy of the insurance certificate can be obtained from the investigator or trial staff.

If you are female and can get pregnant (meaning that you are neither post-menopausal for one year nor surgically sterile) and sexually active, you must avoid getting pregnant in order to take part in this trial. You will be required to agree to use an approved method of birth control beginning 28 days prior to the first trial vaccination and continuing for 3 months after the administration of last trial vaccine. In addition, you will need to have a negative pregnancy test before vaccination. If you suspect that you (or your partner for male participant) have become pregnant during the trial, you must notify your investigator immediately.

There are no costs to you to be in the trial. The sponsor will pay for the trial vaccines and the tests that are part of the trial. You will receive reasonable reimbursement for trial related cost (for example, travel/parking costs and meals).

Your collected personal data will be treated confidentially during the trial.

The documents of the trial have been reviewed by the Belgian competent health authorities (FAMHP) and a Belgian Independent Ethics Committee.

After you complete the trial, you will no longer receive Ad26.COV2.S vaccine.

To participate in the trial, you have the following responsibilities:

- Give correct information about your health history and health condition.
- Tell the trial staff about any health problems you have during the trial**.** Note: you should contact the trial staff as soon as you start experiencing COVID-19 symptoms.
- Talk to your investigator before getting any other licensed vaccines (such as flu vaccine).
- Tell the trial staff about any new medicine or drug you take during the trial
- Complete the electronic questionnaires as directed.
- Provide all required samples, e.g. nasal swabs, saliva and blood samples.
- Attend all trial visits.
- Do not take part in any other medical clinical trials
- Do not receive COVID-19 vaccines other than the one provided through this trial.
- Do not donate bone marrow, blood, and blood products from time of the trial vaccine administration until 3 months after receiving the trial vaccine

If you have any questions about the trial or your rights as a trial participant, please contact the investigator/trial staff or Belgium data protection authorities at the contact details listed in the section “Who can I contact in case of questions?”.

With my best regards,

Your treating physician and investigator.

CHAPTER I – DESCRIPTION OF THE TRIAL AND YOUR RIGHTS WHEN PARTICIPATING

1. Why are we doing this trial

This clinical trial (further on referred to as “trial”) will evaluate the investigational medicinal product (IMP), vaccine called Ad26.COV2.S for the prevention against COVID-19, a disease caused by Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2). The SARS-CoV-2 virus is passed from person to person primarily by small droplets from the nose or mouth when an infected person coughs, sneezes, or speaks. Most people who are infected have mild COVID-19 disease such as cough and extreme tiredness, but some people have severe disease and can even die.

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

The main purposes of this trial are:

- To see if the Ad26.COV2.S vaccine is safe
- To learn more about the side effects caused by the Ad26.COV2.S vaccine
- To see if the Ad26.COV2.S vaccine helps to prevent or lessen the severity of COVID-19 disease.

Ad26.COV2.S vaccine is experimental, which means it is not approved for use by any Regulatory Authority in any country and is not marketed. Therefore, it can only be used in a clinical trial such as this one.

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

The Ad26.COV2.S vaccine includes genetic material from the SARS-CoV-2 virus. When the trial vaccine is injected into your body, the genetic material from SARS-CoV-2 will produce ‘spike proteins’ which are small bits of protein specific to SARS-CoV-2. Our bodies then make antibodies (proteins produced in the blood recognizing foreign invaders such as viruses and bacteria and marking them for destruction) to create 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 trial vaccine.

The investigator or trial staff will discuss with you the requirements to be allowed to enter the trial.

2. Do I have to take part in a trial?

Your participation in a trial is voluntary and must remain free of any coercion. This means that you have the right not to take part in the trial or to withdraw at any time without giving a reason, even if you previously agreed to take part. Your decision will not affect your relationship with the investigator or your treating physician nor will it affect the quality of your future medical care.

If you become sick with COVID-19 (and as explained above, **you cannot get COVID-19 from the vaccine**), the trial staff will monitor you daily and request that you provide extra nasal swabs and saliva samples.

If a vaccine for COVID-19 is authorized for use or approved in your country, you should speak to your investigator to discuss if and when you may be eligible to receive it.

3. What will happen during the trial?

This trial will include about 30,000 participants worldwide, including about 3000 in Belgium. Overall, your participation in the trial will last about 2 years and 3 months and may involve around 10 on-site or telemedicine visits.

The trial will be conducted in two stages. The first stage consists of 1000 participants who are “healthy”, meaning they do not have other health conditions. After they have received the injection of the trial vaccine and have been observed for 3 days following the injection, all the remaining participants will be enrolled.

The trial is divided into 3 parts: 1) Screening Period, 2) Main Trial Period and 3) Follow-up Period.

1

Screening
Visit 1

- Screening is the process where it is determined whether you can participate.
- Screening happens before you receive the first trial vaccine injection.
- If you are considered ineligible for the trial, based on your investigator’s judgment, in certain circumstances, you may be rescreened again. This can happen only one time and you may need to perform all screening procedures again.

2

Main Study Period
Visit 2-8

- The Main Trial Period lasts about 1 year and 2 months.
- You will receive the two trial vaccine injections: on Visit 2 (Day1) and on Visit 4 (Day 57).
- You will use a secure app or website called StudyHub to communicate with trial staff and complete questionnaires.
- You may have up to 7 clinic visits during this period.
- If you develop COVID-19 symptoms, you will have additional visits. You may be asked to do some procedures at home.
- Some of the visits might be a telephone call or home visit by the trial staff or home health care staff.
- If you stop the trial early, you will be asked to complete an Early Exit visit.

3

Follow-up Period
Visits 9-10

- At the end of the Main Trial Period, you will begin the 1-year follow-up period. The purpose of this period is to see how long the vaccine’s protection might last.
- You will use a secure app or website called ‘StudyHub’ to communicate with trial staff and complete questionnaires.
- You will have up to 2 clinic or telemedicine visits during this period.
- If you develop COVID-19 symptoms, you will have additional visits. You may be asked to do some

Some participants will have extra tests and procedures

There are two small groups of participants that will have extra tests and procedures: An Immunogenicity subset and a Safety subset.

The Immunogenicity subset is a small group of about 400 people who will have additional blood draws. The reason for this group is so researchers can take a closer look at their immune responses to the trial vaccine.

The Safety subset is a group of up to 6,000 people who will be asked to complete additional diary questions after each vaccination. The purpose of this group is to collect more information about the safety of the vaccine until 7 days after the day of vaccination.

Participants in Belgium will not be included in these subsets.

Trial procedures and activities

Throughout the trial, you will have your height, weight, blood pressure, heart rate, and body temperature measured, and be asked to answer questions about your general health, medical history and the medications you take. You will be provided with an oral thermometer to measure body temperature, and an oximeter to measure pulse rate and the level of oxygen in your blood. In addition, if you are in the 'Safety subset' you will be provided with a ruler to measure redness or swelling caused by the injection. The table below explains some other procedures that are part of the trial. It is possible that certain on-site trial visits will be replaced by telemedicine visits (a remote visit that is done by a video or phone call) or home visits by trial staff or a vendor.

A caregiver may support you in completing questionnaires when you need help or have questions.

Procedure	**What is it?**	**When is it done?**
Informed Consent	The investigator/trial staff will talk to you about the trial and you will decide if you want to join. You will have the opportunity to read the consent form and ask any questions.	Screening – Visit 1
Lifestyle Characteristics	The investigator/trial staff will ask you about your lifestyle including work, living situation, and community involvement.	Screening – Visit 1 and throughout the trial as needed
Vaccine Administration	The investigator or staff will inject the trial vaccine or placebo into your arm. You may experience redness at the injection site or muscle soreness. You may be asked to stay at the trial site for up to 30 minutes after administration for observation.	Visits 2 and 4
Review of side effects	At each visit, the investigator/trial staff will ask about any side-effects. Side effects are any unexpected or unwanted response that may happen during the trial	Visit 2 and every visit after
Pulse oximetry	A small device called a pulse oximeter will be placed on your finger to measure the oxygen levels in your blood. The device can detect small changes in how efficiently oxygen is	Visit 2 and as instructed if you experience COVID-19-like symptoms

Procedure	What is it?	When is it done?
	being carried through your body. This test is painless.	
Nasal Swab Testing	A cotton swab will be inserted in your nose and rotated to collect a sample of your nasal secretions. You may experience slight discomfort or tickling in the nose with this procedure. It may cause a nosebleed. A nasal swab kit will be given to you so that you can collect nasal samples at home if you develop COVID-19-like symptoms. You will be trained by the site staff on how to use the nasal swab kit, how to store the collected sample (refrigerated), and when/how to return the collected samples to the trial site. The trial site may arrange for supplies to be delivered to your home and for samples to be collected from your home. For this purpose, the trial site may need to share your contact information with a courier.	Visit 2 and as instructed if you experience COVID-19-like symptoms
Saliva Sample Collection	A saliva sample kit will be given to you so that you can collect saliva samples at home if you develop COVID-19 like symptoms. You will be trained by the site staff on how to use the saliva sample kit, how to store the collected sample (refrigerated or at room temperature), and when/how to return the collected samples to the trial site. The trial site may arrange for supplies to be delivered to your home and for samples to be collected from your home. For this purpose, the trial site may need to share your contact information with a courier.	As instructed, if you experience COVID-19-like symptoms

Procedure	What is it?	When is it done?
Electronic Device Questionnaires	You will be asked to respond to questions about your health using an app on your smartphone or tablet or using a secure website (called Study Hub) on your computer. The trial staff may be able to loan	During the Main Trial Period you will be asked to answer questions two

Procedure	What is it?	When is it done?
	you a dedicated smart phone during the trial period if you do not have one. Site staff will show you how to complete the questionnaires. It will take you a few minutes to complete most questionnaires. It may take up to 15 minutes to complete questionnaires when you experience changes to your health. You may receive text messages as reminders to complete these questionnaires. You may have a caregiver or site staff assist with completion of questionnaires as needed. There are 3 types of questionnaires: - For all participants to monitor for any new symptoms or health concerns; - For those who develop symptoms of COVID-19 to provide information about the signs and symptoms they experience (including measuring body temperature, pulse oximetry and heart rate); - For those in the Safety Subset to report reactions after vaccination (including measuring body temperature and measuring any redness or swelling where they received the vaccine).	times per week to monitor for new symptoms or health concerns that could be related to COVID-19. During the Follow Up Period, participants will be reminded to answer these questions two times per month. If you develop signs and symptoms of COVID-19, you are asked to report this immediately via StudyHub. In addition, you be asked to respond daily to questions about the symptoms you have. In addition, participants in the **Safety Subset** will report reactions after vaccination. This will be done on a daily basis until 7 days after the day of vaccination.

Procedure	What is it?	When is it done?
Blood draw/tests	The investigator or site staff will draw blood from a vein in your arm. You may get a bruise or irritation at the place where the needle goes into your skin. Some participants may faint. In rare cases, the blood draw can cause an infection. The total amount of blood that will be drawn during the entire trial is 120.0 mL • For most participants, the total amount of blood drawn during the trial visits will be about 40.0 mL. Up to an additional 30 mL will be drawn from participants who develop COVID-19 like symptoms. You may be asked to repeat a blood test if there are safety or technical issues with the initial draw. Your blood will be used to check • For confirmation of COVID-19 infection • Your immune response to the trial vaccine	Participants not in the Immunogenicity subset will have blood drawn at Visit 2, Visit 5, Visit 7, Visit 8, and at early exit visit if applicable. Participants in the Immunogenicity Subset will have blood drawn at Visits 2, 3, 4, 5, 7, 8, 9, 10 and at early exit visit if applicable. Additional amount will be drawn from participants who develop COVID-19 disease. Sometimes you may need to repeat a blood test.
Urine sample	If you are a female who could get pregnant, we will collect a urine sample from you to check for pregnancy before administration of the trial vaccine.	Visit 1, Visit 2, and Visit 4
Sample collection for scientific research	Any of your blood samples could be used for scientific research as described in Chapter I, § 11.2 “What will happen to the collected biological samples?” You will be informed if testing on your samples for this trial changes.	Visit 2 and as instructed if you experience COVID-19 like symptoms

If Home Health Care Visits Will Occur

Marken arranges for qualified and trained health care professionals ("HHCP") to go to subjects' homes during clinical trials, to make clinical trial participation as easy as possible for subjects.

Your investigator will provide Marken with your contact details (name, email, address, and telephone number). Marken will then share your information with the assigned medical professional who will perform the trial visit. The medical professional will contact you to schedule the visit. The medical professional will arrive at your preferred location and will perform the procedures and capture any visit data within Marken's Home Healthcare System. The medical professional might also request information regarding your current health issues. This data will be available to your trial site via the Marken's Home Healthcare System available for your trial staff to view and use per trial requirements. Your investigator will review the visit data and may request that you visit the trial site for a follow-up visit if needed.

You have the right to cancel a Home Health Care visit at any time. You also have the right to opt out of Home Health Care visits at any time. Your participation in this trial is not dependent on your acceptance of a Home Health Care visit. If you decide to cancel a Home Health Care visit, please notify your investigator so that the visit can be rescheduled as needed. Your decision to opt in or opt out of a Home Health Care visit will not affect your regular trial participation

StudyHub

A secure online platform called StudyHub will be used in this trial. The sponsor is working with IQVIA (a clinical research organization) to use StudyHub to support this trial. StudyHub is the place for you to communicate with trial staff, complete trial tasks and find important information about the trial. You will access StudyHub using a secure app on your smartphone or tablet or by using a secure website you can access through any computer.

To access StudyHub, you will need to set up an account. If you choose to use the application on a smartphone or tablet, your trial team will assist you in the set-up and you will receive notifications through email at first. Once your account has been set up, you can change your notification preferences in the app settings. If you choose to use StudyHub on a web browser, you will receive account setup and instructions and trial notifications via e-mail.

The trial staff may be able to loan you a dedicated smart phone to access StudyHub if you do not have one. You will have to return this device at the end of the trial.

There is a service called the "Study Concierge" that is accessible to you 24 hours/day, 7 days/week if you have questions or need technical assistance with StudyHub. The Study Concierge is a centralized support managed by IQVIA on behalf of your trial site staff. You can reach the Study Concierge through StudyHub. However, all medical questions should be directed to your trial site staff.

Some of the trial procedures may be done through StudyHub. If the trial staff conducts a telemedicine visit, they will use the secure connections and may ask you to turn on the camera on your device so that you can see each other during the call. The trial staff can tell you more about this.

What injection will I receive?

Not everyone in the trial will receive Ad26.COV2.S vaccine. You will either get injected with the Ad26.COV2.S vaccine or with a placebo. The placebo looks just like the trial vaccine and is given the same way (by injection) but has no active vaccine in it. The placebo in this trial will be sterile saltwater.

A computer will randomly assign you to either group by chance, like flipping a coin. You will have a 50% chance of being put in either group:

- Group 1 – Ad26.COV2.S vaccine on Visit 2 and Visit 4
- Group 2 –Placebo injections on Visit 2 and Visit 4

During the trial, neither you nor the trial staff will know which group you're in. In a medical emergency, the trial staff can quickly find out which group you're in.

How is the trial vaccine given?

The trial vaccine is given by injection. The needle is put into the muscle in your upper arm. When possible, the injection will be given in the arm you use less. This will be done at Visit 2 (Day 1) and Visit 4 (Day 57).

You will remain at the trial site for observation for up to 30 minutes after receiving the vaccine.

If you meet all the conditions required to be enrolled in the trial and agree to take part in the trial, you will undergo the above-mentioned tests and examinations. If you have any important side effects, the investigator might determine that it is necessary to perform additional tests which will be considered as specific to the trial.

What if I get COVID-19 during the trial?

When you enroll into the trial, you will be asked to provide the name of your treating physician and the hospital you would likely seek care at if you become seriously ill. This is so we can be sure to follow you to check your health. You should contact the trial staff as soon as you start experiencing COVID-19-like symptoms. If you have a COVID-19 test performed outside of the trial laboratory (or facilities), and the result is positive, you should inform the trial staff immediately even if you do not have any symptoms. Trial staff will monitor your health and may visit you in your home. If you seek health care for COVID-19 by a nurse or doctor at a clinic, Emergency Department, or hospital, we ask that you bring a form with you to present. The trial staff will give you this form at the start of the trial and provide you instructions on what to do with it. It is important that you keep this form in a safe place while you are participating in the trial. If you turn out to be positive for COVID-19, local guidelines may mandate the trial staff to inform the local health authorities to initiate the contact tracing system.

4. Will I benefit from the trial?

The information obtained during a trial may contribute to a better understanding of the use of the investigational medicinal product (referred to as "IMP") or to the development of a new vaccine for the protection of yourself or future patients.

The IMP may or may not be beneficial in protecting you against COVID-19 or relieving your symptoms. Even if it is beneficial to you, a potential return or worsening of symptoms is still possible.

5. What are the possible risks and discomforts of taking part?

5.1. What are the possible side effects of Ad26.COV2.S vaccine?

Participation in a trial involves some risk.

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

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

malaria. As of 4 September 2020, approximately 114,000 participants were vaccinated with Ad26-based vaccine in ongoing trials, including an ongoing government-led immunization campaign in Rwanda (UMURINZI Ebola Vaccine Program campaign). Pain, tenderness and redness at the injection site, headache, chills, joint pain, muscle pain, tiredness, generally not feeling well, nausea and fever have been seen with these trial vaccines. These reactions usually start within 1 to 2 days after the injection and most of the reactions get better within 1 to 3 days.

As of 10 September 2020, a single injection of Ad26.COV2.S vaccine has been administered to 805 human participants, aged 18 and older. Following administration of Ad26.COV2.S vaccine, fever, fatigue, muscle aches and headache appear to be more common in younger adults and can be severe. For this reason, we recommend you take a fever reducer or pain reliever if symptoms appear after receiving the vaccination, or upon your investigator's recommendation. Please tell the trial staff if you take anything.

In a Phase 3 trial of Ad26.CoV2. S vaccine, one trial participant developed a serious condition, a clot in a blood vessel in the brain that then resulted in bleeding into the brain. Symptoms included severe and persistent headache, confusion, blurred vision, and seizures. There are many possible factors that could have caused the event. After a thorough evaluation, no clear cause has been identified. At this time, it is unknown if the vaccine caused this condition, however, the possibility that the vaccine may have contributed to this event cannot be excluded.

If you develop symptoms like severe and/or persistent headache, confusion or blurred vision, you should promptly notify your healthcare provider and/or trial staff.

Some vaccines may cause a more severe course of disease 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, trials 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 infection cannot be absolutely ruled out with the vaccine tested in this trial. Because of this, all participants in this trial will be monitored for vaccine-enhanced disease throughout the trial. We will do this by taking nasal swabs in participants suspected of having SARS-CoV-2 infection. Trial participants with a positive test result will be followed until the sign and symptoms have been resolved. These procedures will allow us to recognize and intervene early in the course of disease. Early recognition and intervention will reduce the risk of a bad outcome if enhanced disease, should it occur.

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

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

Risks and possible side effects of vaccines in general

All types of injections can cause:

- Stinging, itching, arm discomfort, pain, soreness, redness, hardness, bruising and swelling where you got the injection
- Fever
- Chills

- Rash
- Itching in other areas of your body
- Aches and pains
- Muscle and joint pain
- Throwing up and nausea
- Headache
- Dizziness
- Feeling very tired
- Fainting

These side effects usually last 2 to 3 days.

Rarely, people may have more severe side effects that limit their normal activities or make them go to the doctor.

If you are feeling very tired, fainting or having dizziness please do not drive or use machines.

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 trial staff will watch you for at least 30 minutes after each injection.

Always tell the trial 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 trial site, contact the emergency number and get medical help right away.

Risk of testing positive for SARS-CoV-2 antibodies

If you receive the AD26.COV2.S vaccine (instead of placebo), your body may have an immune response to the specific coronavirus protein that is part of the vaccine. This immune response will not affect any results of COVID-19 tests, whether taken as part of the trial or outside of the trial, 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 trial staff will provide you with additional information and help you get the right test.

Antibodies and pregnancy

If you become pregnant during or after the trial 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.

Confidentiality

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

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

Because this IMP is still under investigation, other currently unknown risks and discomforts could occur. **Therefore, it is very important that you report <u>any</u> new or worsened health problems immediately to the investigator, regardless of whether or not you think it has to do with the trial (or to Ad26.COV2.S vaccine), and even when it is already described in this document. If you need to use other medication, discuss this with the investigator before taking it. If, for any reason, you consult another treating physician during the trial you must inform him/her that you are taking part in a trial and present your emergency card. This could be important in determining a diagnosis and giving you the correct treatment if needed.**

5.2. Can I take <u>other medicines</u> during the trial?

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

Tell the trial staff about any new medicine or drug you take during the trial, including over-the-counter drugs (for example, to treat side effects after the injection). Also, tell the trial staff about any changes to your ongoing medicines or drugs.

Will my participation to the trial have an <u>impact on my daily activities</u>? Overall	
Do	**Do not**
• Give correct information about your health history and health condition. • Tell the trial staff about any health problems you have during the trial**.** Note: you should contact the trial staff <u>as soon as</u> you start experiencing COVID-19 symptoms. • Talk to your investigator before getting any other licensed vaccines (such as flu vaccine). • Complete the electronic questionnaires as directed. • Provide all required samples, e.g. nasal swabs, saliva and blood samples. • Attend all trial visits.	• Do not take part in any other medical research trials • Do not receive COVID-19 vaccines other than the one provided through this trial. • Do not donate bone marrow, blood, and blood products from time of the trial vaccine administration until 3 months after receiving the trial vaccine

5.3. Can my partner or I get <u>pregnant</u> or can I breastfeed during the trial?

This section is intended solely for participants with a potential to get pregnant or participants who may get their partners pregnant.

Animal trials have shown that Janssen's licensed Ad26-based vaccine against Ebola did not raise concerns in preclinical reprotoxicity trials. These are trials in pregnant animals that received the vaccine, and then delivered animal babies. Therefore, ongoing trials with the Ebola vaccine allow pregnant women and women planning to become pregnant to receive

that vaccine. However, these trials are not yet available for Ad26.COV2.S. For this reason, in this trial, we will not enroll pregnant women or those who aim to get pregnant within 3 months of receiving the trial vaccine. The appropriate animal trials are currently underway.

Female Participants Who Cannot Get Pregnant

If you are postmenopausal for at least one year or have had a total hysterectomy (surgical removal of the womb) or surgical removal of both ovaries or surgical removal of both fallopian tubes, you cannot get pregnant. Therefore, the section about contraceptive use does not apply to you.

Female Participants Who Can Get Pregnant

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

Birth control methods that can be used while in this trial 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 until at least 3 months following the last trial vaccination)

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

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 trial vaccine administration to demonstrate that you are not pregnant.

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

<u>Male participant</u>:

If you take part in the trial, you commit to inform your female partner of your participation in this trial and of the potential risk to an unborn child and you can use contraception.

If your partner becomes pregnant during the trial, you should tell the investigator immediately. Your partner will be asked for permission to allow the investigator 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.

6. What If something goes wrong within the trial?

Even if there is no fault, the sponsor is liable for harm caused to you whether directly or indirectly related to your participation in the trial. The sponsor has taken an appropriate insurance (a so called “NO FAULT INSURANCE”) for this liability (Ref. 1). A copy of the insurance certificate can be obtained from the investigator or trial staff.

If you (or in the event of death, your rightful claimants) seek compensation for a harm to your health as a direct or indirect result of participating in the trial, you must inform your investigator or trial staff promptly.

If the investigator believes that a link between the new or worsened health problem(s) and the trial is possible, he/she will inform the trial sponsor. The sponsor will then immediately initiate the declaration procedure to its insurance company. If the company considers it necessary, it will appoint an expert to assess whether there is a link between your reported health problem(s) and the trial. The insurance does not cover the natural progression of your disease/condition or the known side effects of the treatment you would have received without taking part to the trial (*that is* your standard treatment).

Whenever you feel it is appropriate or if you or your rightful claimants disagree either with the investigator or with the expert appointed by the insurance company, you may contact the insurance company or proceedings may be brought against the insurance company. You will find the contact details in section “Who can I contact in case of questions?” on the front page of this form.

7. What if new information on the IMP become available during the course of the trial?

During the course of the trial, important new information might become available, possibly affecting your decision to (further) participate. For example, important new information on the IMP may become available. It is the duty of the investigator to discuss this new information with you and to give you the opportunity to re-consider your participation in the trial.

If you decide to stop taking part in the trial or if you are no longer able to participate, your investigator will see to it that you continue to receive the best possible medical care.

8. Can my participation in the trial end prematurely?

As explained in detail below, your trial participation may end prematurely when

- you decide to withdraw your consent,
- the investigator decides to end your trial participation, or
- other entities interrupt or end the trial.

In any case, if your trial participation ends prematurely, the investigator will discuss your future medical care with you, if needed. The sponsor can continue to retain and use any data that have already been collected before the end of your participation. This is to avoid skewing / biasing results of the trial (as described in Chapter I, § 11.4. “How will my data be handled?”).

If you experience a side effect at the moment of stopping the IMP, the investigator may contact you in the future to see if it has resolved or not after the end of the trial participation.

If you experience a new side effect after the end of your trial participation you may contact the investigator to ask for a follow-up.

8.1. What happens if another vaccine is marketed and available in Belgium during the course of the trial?

If another vaccine is marketed and available in Belgium during the course of the trial, it may be possible for you to obtain said vaccine at your initiative and you may request your trial center to inform you whether you have received Ad26.COV2.S vaccine or placebo in this trial. Further information about that process are described in additional document: Informed Consent Form Addendum Regarding Emergency Use of Authorized or Licensed COVID-19 Vaccines.

8.2. You decide to withdraw your consent

You are entitled to withdraw your consent for any reason, at any time, without having to justify your decision. However, for your safety, you should inform the investigator of your decision. Although it is not mandatory, it may be useful for the investigator and for the sponsor to know the reason of your decision (for example side effects, frequency of clinical visits,…).

If you withdraw your consent, this means you decide to stop

- the treatment with the IMP, and
- all trial-related visits and examinations.

Please discuss with your investigator to evaluate the practical modalities of your withdrawal (in light of your situation), including any follow up-visits or procedures.

In any case, no new data will be sent to the sponsor.

If your biological samples (e.g. blood samples, urine samples) have already been used or analysed before the withdrawal of your consent, the sponsor still has the right to use the results from those tests.

The biological samples that have been collected (but not tested) before the withdrawal of your consent and the data obtained from it, can also still be used by the sponsor. You may ask for a destruction of those samples. If this impacts the validity of the trial, the destruction may be postponed till the end of the trial.

In case you have signed an additional consent form for the use of your samples in future research, and you choose not to withdraw this separate consent, your samples can still be used for this research.

8.3. The investigator decides to end your trial participation

The investigator may end your trial participation because

- you become pregnant during the trial,
- it is better for your health,
- he/she determines that you are not following the instructions given to participants, or
- any other reason that will be explained.

8.4. Other entities may interrupt or end the trial

The sponsor and the competent Belgian health authorities may interrupt or end the trial because

- the information gathered shows that the IMP is not effective (does not deliver a sufficient level of improvement in the health of the trial participants),

- the IMP causes more (serious) side effects than anticipated, or
- any other reason that will be duly motivated by such party.

8.5. What happens if I stop the study early?

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

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

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

9. Which treatment will I get after my participation in the trial?

After you receive the 2 IMP injections, the investigator will assess your health. After you complete the trial, you will no longer receive Ad26.COV2.S vaccine. If you received the placebo, you may be offered the trial vaccine at no cost if and when the trial vaccine has been shown to be safe and that it works, but it is possible that this may not occur until 2 years after vaccination. This will be determined after consultation with the national health authorities in Belgium.

10. Will my participation in the trial involve extra costs for me?

10.1. Examinations and treatments paid by the sponsor

The sponsor has arranged to compensate the hospital or site for

- the time devoted to the trial by the investigator and the trial staff,
- the visits/consultations and all scheduled examinations specific to the trial,
- the investigational treatment (IMP and any other medication and material specifically used for the trial).

In Chapter I, § 4. “What will happen during the trial?” you will find the treatments or examinations that you will have to undergo. The treatments and examinations that are trial specific will be paid by the sponsor and will not be charged to you.

If you need more details or if you are not affiliated with a mutual insurance fund (Belgian social security), please contact the trial staff.

The visits and treatments which are a consequence of a side effect are also considered as trial specific.

10.2. Other expenses paid by the sponsor

You will receive a compensation for the following expenses:

Type	**Amount**

Travel costs up to 100 km (paid to the caregiver only when a caregiver is joining you)	€25 per visit paid by means of 2 vouchers with a value of €12.5 each OR €25 per visit paid in cash
Travel costs above 100 km (paid to the caregiver only when a caregiver is joining you)	€50 per visit paid by means of 4 vouchers with a value of €12.5 each OR €50 per visit paid in cash
Time investment and effort for on site visits	€137.50 per visit paid by means of 11 vouchers with a value of €12.50 each OR €137.50 per visit paid in cash
Time investment and effort for home visits	€37.50 per visit paid by means of 3 vouchers with a value of €12.50 each OR €37.50 per visit paid in cash

The trial staff shall contact you for the practical arrangements.

11. Which data are collected about me during the trial and what will happen with them?

11.1. Which data are collected and processed during the trial?

The collected and processed personal data concern information about your health and medical condition. This includes your medical history, some of your background information (for example your age, sex, and ethnic origin) and the results of examinations required by the trial.

The trial staff will also collect, record, and use personal information about you, for trial purposes only, within StudyHub, which is a secure internet portal. Your personal information collected in StudyHub may include:

- Demographic information such as your name, your study ID #, home address, e-mail address, telephone/mobile number, date of birth, and gender which will be entered into StudyHub to create your account;
- Contact information about your emergency contact; and caregiver, if applicable
- The name of your regular doctor and the hospital where you would likely seek care if you become seriously ill with COVID-19
- Sensitive information about your physical or mental health or condition
- Information from the questionnaires you are asked to complete
- If you wish, you can upload your photograph to StudyHub but you do not have to.

The site will use some of your demographic information to create your account in StudyHub and help you download the StudyHub application to your device when you enroll. You will also be able to manage and update your user profile and adjust preferences about communications and language. All information which is collected about you in StudyHub

that is exported for the purposes of medical, or regulatory activities related to the trial research or to analyze the trial data will be identified only by your subject number. Only the investigator and the trial staff (including the Study Concierge [as described in Chapter I, §3.What will happen during the trial?, StudyHub] on behalf of the trial staff) will have access to information that can link you to your subject number; this information will not be shared outside of the StudyHub portal unless necessary for safety purposes.

If you agree, we will collect information regarding your current work, your living/housing situation, and your social interactions. The purpose of this is to see if we can identify work, living or social situations that are associated with COVID-19 disease. You are not obligated to share this information: you can accept or refuse to provide this information.

11.2. How will the investigator treat my personal data?

The investigator is bound by professional secrecy about the data collected.

This means that he/she will never reveal your identity, including in a scientific publication or a lecture and that he/she will encode your data (*that is* by replacing your identity by an identification code in the trial) before sending them to the sponsor.

Therefore, the investigator and the trial staff under the responsibility of the investigator, will be the only ones able to establish a link between your identity and the data transmitted during the trial, with the exceptions listed under section 11.6. “Who, other than the Investigator and his staff, has access to my personal data?”.

The data transmitted to the sponsor will not allow the sponsor to identify you.

11.3. What will happen to information about me collected during the trial?

Your participation in the trial means that your personal data

- are collected by the investigator, and
- are used in an encoded form by the trial sponsor.

The investigator and the sponsor can only use the encoded personal data for research purposes in connection with scientific publications within the context of the trial that you participate in, or for a broader use of the encoded data if described below.

In addition, the sponsor may provide access to the encoded data to external researchers (that are not involved in this trial). In the event an external researcher wants to use the data in a project not yet described in this document, this project will have to be approved by an Ethics Committee. If your encoded trial data are sold, you will not benefit from this.

11.4. Remote access to your records at the trial site

Representatives of the sponsor (e.g., monitors, auditors) may use an electronic tool to access your personal data remotely. This electronic tool provides a secure electronic gateway between the investigator and trial 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.

11.5. How will my data be handled?

Your trial data will be processed in accordance with the General Data Protection Regulation (GDPR, Ref. 2) and the Belgian law on data protection of 30th July 2018 (Ref. 3). The sponsor is responsible for this processing.

Processing your personal data in this trial is allowed because we are conducting scientific research and you have given your **consent.**

11.6. Do I have access to my data collected and processed during the trial and can I rectify them?

You are entitled to ask the investigator what data are being collected about you and how those data will be used in connection with the trial.

You have the right

- to inspect and access these data
- to receive the personal data that are collected
- to ask for correction if they are incorrect

It is not possible (to avoid skewing of the results in the trial)

- to have all your data erased
- to restrict the processing of your data.
- to object to the processing of your personal data

11.7. Who, other than the Investigator and his staff, has access to my personal data?

To verify the quality of the trial, it is possible that your personal **un**coded data or information in your medical records relevant for the trial, will be examined by people outside the trial staff but under the responsibility of the investigator. These persons must be subject to professional secrecy or a confidentiality agreement. The following might be considered:

- the personnel designated by the sponsor of the trial (MONITORS and AUDITORS), and people or organisations providing services for or collaborating with the sponsor. They will however never transfer your name and contact details to the sponsor.
- inspectors of competent health authorities worldwide
- an independent audit group
- people designated by the Ethics Committee

For the needs of the trial, the encoded trial data may be sent to other EU and non-EU countries and may be reviewed by

- personnel (other than the inspectors) of competent health authorities of Belgium (Federal agency for medicines and health products, FAMHP) and other EU and non-EU countries,
- the evaluating Belgian Ethics Committee(s),
- external researchers,
- the sponsor of the trial, personnel designated by the sponsor, and people or organisations providing services for or collaborating with the sponsor, and/or
- group companies of the sponsor in Belgium, and in other EU and non-EU countries.

The European regulation and the Belgian legislation on data protection have requirements for transferring data to non-EU countries. The sponsor must ensure equivalent guarantees regarding personal data protection standards before transferring the encoded data to non-EU countries. If for this purpose, there is a data protection agreement, a copy of this agreement may be obtained via the investigator. You can always contact your investigator to obtain more information about any such transfers.

11.8. How will your personal data be protected in StudyHub?

Your records will be kept secure during this process.

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

When becoming a StudyHub user, you will be presented the End User License Agreement and Privacy Policy linked to StudyHub, 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 trial activities have been completed or you have withdrawn from the trial, you can remove the StudyHub application from your phone by following your device's standard procedures for removing applications. You can contact the StudyHub team if you need assistance with this.

After all participants have completed the trial, the StudyHub application will be deactivated.

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

Marken and their courier (for example for blood draw samples) will manage your personal data (information about you) in compliance as outlined above. This remains also valid for Home Health Care, with the exception that your contact details will be disclosed and processed by Marken and their courier and the assigned medical professional as required for the performance of Home Health Care services as described in this form.

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

All the information collected by Marken will be processed in accordance with the GDPR.

11.10. What will happen to the results of the trial?

After trial closure, a description and the results of this clinical trial will be published in specialised medical journals. A copy of the scientific publication or a summary for laypersons can be obtained from the investigator or the trial staff.

A description of the trial will also be available on https://www.clinicaltrialsregister.eu/ and/or https://www.Clinicaltrials.gov. You can search these websites at any time using the trial number given on the front page of the informed consent form. The websites will include a summary of the results within 1 year after the end of the trial (Ref. 4).

These websites or publications will not include information that can identify you.

11.11. Will my data be used for other purposes than for the trial in which I take part?

The results of the trial will be used to answer the scientific questions of the trial. In addition, the sponsor would like to use your data obtained from this trial, in connection with other research and development activities (and the associated scientific publications). These activities may concern

- the way Ad26.COV2.S and vaccines of the same group work,
- COVID-19 and associated health problems for which Ad26.COV2.S is evaluated in this trial,
- develop diagnostic tests,
- learn from past trials to plan new trials or improve scientific analysis methods,
- publish research results in scientific journals or use them for educational purposes.

Any additional research outside of the trial, must be approved by a Belgian recognized Ethics Committee.

At the end of this form you agree or disagree to the use of your trial data for other purposes by ticking the appropriate check-box in Chapter II – Informed consent.

11.12. How long will my data be kept?

After the end of the trial your encoded data will be retained for at least 25 years (Ref. 5) to ensure the validity of the research. This will also be the case if you stopped trial participation prematurely.

12. Which biological samples are collected from me during the trial and what will happen with them?

12.1. Which biological samples are collected from me during the trial?

Biological samples are samples of human body material (for example blood, tissue, urine, faecal stool, ….)

In this trial, the following biological sample(s) will be taken: urine, blood, saliva and nasal swab.

12.2. What will happen to the collected biological samples?

The collected biological samples will be managed and stored until final analysis are completed at Janssen Vaccines and Prevention B.V. Archimedesweg 4, 2333 CN Leiden, The Netherlands; or analysis labs contracted under a Laboratory Service Agreement by Janssen Vaccines & Prevention B.V.; and Covance Central Laboratory Sàrl**,** Rue Moïse-Marcinhes 7**,** 1217 Meyrin**,** Genève**,** Switzerland, until final analysis is completed, unless you consent to the future use of your samples described in Chapter I, § 12.4. “What happens with any remainders of biological samples once the analyses described in this document have been carried out?”.
The sponsor may use any of your samples collected during this trial to:

- Understand how the Ad26.COV2.S vaccine works, or why it may cause side effects
- To better understand COVID-19 disease
- Understand why people may respond differently to Ad26.COV2.S vaccine
- To better understand vaccines made from adenoviruses
- To develop tests for Ad26.COV2.S vaccine and SARS-CoV-2 infections.

The results of tests done on your samples are only for use in scientific research. They will not be used for your medical care or to make a diagnosis about your health. However, if you have a positive test result for SARS-CoV-2 blood analyses due to exposure to the virus, you will be informed of the result by the trial staff.

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

If you do not want these analyses to be conducted, you will not be allowed to participate in the trial. 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 trial.

12.3. How will my biological samples be handled?

The procedure to encode your biological samples is the same as that used for your personal data (see Chapter I, § 11.3. “What will happen to information about me collected during the trial?”, Ref. 6). Samples sent to the sponsor or to organisations working in collaboration with the sponsor, will only be labelled with your trial identification code.

As part of the trial, the sponsor might transfer (a part of) your samples to a laboratory that is working with them. This laboratory may only use your samples as specified in this document. The tracking of your samples will be ensured by the sponsor unless you have accepted anonymization of your samples.
Your samples may be sent to the sponsor and other members of the Johnson & Johnson group of companies and to contractors working for them. Your samples may also be shared with other researchers. Your samples will not be sold or given to any other groups for their use. Researchers working with the sponsor are not allowed to share samples with anyone who is not authorized by the sponsor.
Your biological samples are deemed to be a “donation”. You will not receive any financial benefit associated with the development of new therapies derived from the use of your biological samples, and which may have commercial value.

You are providing your samples, for use by the sponsor. The sponsor (and research partners, where applicable) will own the use of the results, treatments, or inventions that can be made from this research.

12.4. What happens with any remainders of biological samples once the analyses described in this document have been carried out?

The sponsor shall use the biological samples within the context of the trial as described above. Since scientific progress in this area is constant, the sponsor would like to, with your consent retain the remainders of your biological samples for up to 15 years. The sponsor will use them for future research, outside the trial that you will participate in, to better understand the disease and Ad26.COV2.S vaccine. Testing will depend on the available technology at the time of testing. Additionally, your samples could be used for research on future COVID-19 vaccines or other viral respiratory disease vaccines. The retention of the remainders of your samples goes together with the retention of the accompanying encoded personal data. The sponsor plans to keep the samples securely at CSM Europe sa (Biorepository (GATE G), Watson & Crick Hill, Rue Granbonpré 11B-1435 Mont-Saint-Guibert, Belgium) or CSM Biomedical Sample Management Inc. (180 Gordon Drive Suite 109, Exton, PA 19341, USA). The samples may be relocated at any time by the sponsor.

You agree or disagree to the retention of the remainders of your biological samples for future research by ticking the appropriate check-box in Chapter II – Informed consent. You may opt out of future use of your samples or withdraw your consent at any time by notifying your investigator. If you withdraw consent for future use of your samples, your samples will be destroyed after they are no longer required for the main trial. 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.

If you agree, any future research, additional to what is described above, may only be conducted according to the legislation on the use of human tissue material (Ref. 7) and with the approval of a Belgian recognized Ethics Committee.

12.5. Will any additional biological samples be collected and used for additional research?

In this trial, no additional biological samples will be collected.

13. Who has reviewed and approved the trial documents?

The documents of the trial have been reviewed by

- The Belgian competent health authorities (FAMHP) or if applicable by the competent national health authorities of other EU members states and
- An independent Belgian Ethics Committee

It is the task of the competent health authorities and the Ethics Committees to protect people who take part in a trial. The health authorities will ensure that the trial is conducted in accordance with the applicable legislation.

You should not under any circumstances take their approval as an incentive to take part in the trial.

14. What happens in case of incidental findings?

If by chance and in addition to the trial objectives a result is discovered during the trial that may be important to your health or the health of your blood relatives (called ”incidental findings”), the sponsor will inform the investigator. With your consent the investigator will notify you and your treating physician about your results and potential consequences. If necessary, the investigator and/or the treating physician will advise you on the next steps.

You agree or disagree to being informed of it by ticking the appropriate check-box in Chapter II – Informed consent.

CHAPTER II - INFORMED CONSENT

PARTICIPANT

PREREQUISITES FOR YOUR PARTICIPATION IN THE TRIAL

- I declare that I have been informed of and that I understand the purpose of the clinical trial, its duration, possible risks and discomforts, the precautions that I have to take and what is expected of me. My rights have been explained to me and I have understood those rights.
- I have had enough time to think about taking part in this trial and to discuss it with a trusted person (for example friends, relatives, treating physician, …).
- 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 trial is voluntarily and free from any coercion and that I am free to stop at any time my trial participation.
- I understand that data about me will be collected and that they will be treated confidentially.
- I agree to my personal data being processed as described in Chapter I, § 11. “Which data are collected about me during the trial and what will happen with them?”.
- I understand that the sponsor has taken out an insurance in case I should suffer any damage in connection with my participation in this trial.
- I understand that when participating in this trial, I will not have any costs except those related to the standard of care treatment of my disease.
- I agree to my treating physician(s) being informed of my participation in this trial.
- I agree not to take part in any other trial at the same time without first informing the investigator or the trial staff, who might not permit me to participate for a good reason.
- I understand that I need to cooperate and follow the investigator’s and trial staff’s instructions regarding the trial.
- I understand that participation to the trial might end for me without my consent if I need other treatment, do not follow the trial plan, have a trial-related injury, or for any other justified reason.
- I certify that all the information I have given about my medical history is correct. I understand that my failure to inform the investigator or designee about any exclusion criteria may harm myself.

OPTIONAL CONSENTS WHICH ARE NO PREREQUISITE FOR YOUR PARTICIPATION IN THIS TRIAL.

1. As specified in Chapter I, § 11. “How long will my data be kept?”, the sponsor would like to be able to use your data obtained from this trial in connection with other research and

development activities (and the associated scientific publications) on the condition that such research purposes have been approved by a Belgian recognized Ethics Committee.

Do you agree with the use of your data obtained in this trial for other research purposes?

(Tick as appropriate. If you leave this question open, we assume the answer is 'I do not agree'.)

☐ **I agree**	☐ **I do not agree**

2. As specified in Chapter I, § 12.4. "What happens with any remainders of biological samples once the analyses described in this document have been carried out?", the sponsor would like to retain the remainders of your biological samples for 15 years for future research outside the trial that you will participate in. The samples will be used to better understand the disease, its treatment and the responses to this treatment, and Ad26.COV2.S.

   Do you agree with the retention of the remainders of your biological samples and the accompanying personal data for future research outside the trial?

   (Tick as appropriate. If you leave this question open, we assume the answer is 'I do not agree'.)

☐ **I agree**	☐ **I do not agree**

3. As described in Chapter I, § 12. "Which biological samples are collected from me during the trial and what will happen with them?", and § 14 "What happens in case of incidental findings?", it may happen that incidental findings are discovered that may be important to your health or the health of your blood relatives.

   If this happens: do you want the investigator to inform you (directly or via your treating physician) of this result?

   (Tick as appropriate. If you leave this question open, we assume the answer is 'yes, I want to be informed'.)

☐ **No, I do not want to be informed**	☐ **Yes, I want to be informed**

I consent to take part in the trial, with the above restrictions and I have received a signed and dated copy of all pages of this document.

Participant's surname and first name:

Date (DD/MMM/YYYY):

Time:

Participant's signature:

IMPARTIAL WITNESS / INTERPRETER (REF. 8)

I, the undersigned (Tick as appropriate),

☐ Impartial Witness

☐ Interpreter

was present during the entire process of informing the participant and I confirm that the information on the objectives and procedures of the trial was adequately provided, that the participant (or his/her legal representative) apparently understood the trial and that consent to participate in the trial was freely given.

I declare furthermore that acting as an impartial witness, I am independent of the sponsor and the investigator.

Impartial Witness / Interpreter surname and first name:

Impartial Witness / Interpreter qualification:

Date (DD/MMM/YYYY):

Time:

Impartial Witness / Interpreter signature:

INVESTIGATOR

I, the undersigned investigator, confirm that

- the participant has been verbally provided with the necessary information about the trial, has been explained the content and has been given an original signed document.
- I have verified that the participant has understood the trial.
- I have given the participant sufficient time to agree to take part and to ask any questions.
- no pressure was applied to persuade the participant to agree to take part in the trial.
- 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 (Ref. 9).

Investigator's surname and first name:

Date (DD/MMM/YYYY):

Time:

Investigator's signature:

GLOSSARY

FAMHP: Federal agency for medicines and health products

IMP: investigational medical product

NO FAULT INSURANCE:

The sponsor is liable for any injury or any damage that the participant has suffered, and which is directly or indirectly related to the clinical trial. You do not have to prove any mistake in this respect.

MONITOR and AUDITOR

Both the monitor and auditor work for the sponsor.
The monitor takes care of a continuous quality check during the course of a trial. The auditor performs a quality check after the trial. They verify if the trial is being/was conducted according to the protocol, if the reported data are liable and if the clinical trial was conducted according the applicable rules.

REFERENCES

[1] This is in accordance with Article 29 of the Belgian Law of 7 May 2004 related to experiments on humans.

[2] General Data Protection Regulation No 2016/679 of the European Parliament and of the council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC.

[3] The Belgian Law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data.

[4] In accordance with section 4.3. of the Commission Guideline: Guidance on posting and publication of result-related information on clinical trials in relation to the implementation of Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006 - (2012/C 302/03). [From the moment the Clinical trial regulation enters into force : In accordance with article 37 of the Clinical trial regulation No 536/2014 of the European Parliament and of the council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC; sponsor have to provide summary results of clinical trials in a format understandable to laypersons.]

[5] In accordance with article 58 of the Clinical trial regulation No 536/2014 of the European Parliament and of the council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

[6] Belgian Law of 19 December 2008 on the acquisition and use of human body material with a view to medical application to humans or scientific research, and the applicable royal decrees.

[7] This is in accordance with Article 21 of the Belgian Law of 19 December 2008 on the acquisition and use of human body material with a view to medical application to humans or scientific research, and the applicable royal decrees.

[8] Use of an impartial witness is necessary when either the subject or the subject's legally authorized representative speaks and/or fully understands the language of the approved informed consent form, but cannot read and write due to any physical impairment or is visually impaired. An interpreter is necessary when the investigator doesn't speak the language of the patient.

[9] Belgian Law of 7 May 2004 related to experiments on humans, and the applicable royal decrees.