Southampton NIHR Clinical Research Facility
University Hospital Southampton NHS Foundation Trust
C Level West Wing, Mailpoint 218
Southampton
SO16 6YD
Tel: 023 8120 4989
Email: uhs.covid19paedvaccinestudies@nhs.net
Website: www.uhs.nhs.uk/nihr-crf

Young Persons Participant Information Sheet & Permission Form

Study Title: A Randomized, Double-blind, Placebo-controlled Phase 2a Study to Evaluate a Range of Dose Levels and Vaccination Intervals of Ad26.COV2.S in Healthy Adults Aged 18 to 55 Years Inclusive and Adults Aged 65 Years and Older and to Evaluate 2 Dose Levels of Ad26.COV2.S in Healthy Adolescents Aged 12 to 17 Years Inclusive

Protocol Number: **VAC31518COV2001: Phase 2**

Principal Investigator: Dr Katrina Cathie
Telephone Number: 02381 203853

Janssen Vaccines & Prevention B.V. (Sponsor)

Biomedical Advanced Research and Development Authority (BARDA)

Represented by: Global Clinical Operations UK, Janssen Research & Development, Janssen-Cilag Limited, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4DP

Please read this information carefully

You are being invited to be in a research study. You may be being asked to sign this consent form in addition to the assent you already signed because you became an adult during the course of the study.

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

1. Taking part in a research study is voluntary and is not part of your regular health care.
2. Our scientific question is: does the study vaccine protect people from getting COVID-19 disease?
3. If you join, your participation in this study will last about 19 months.
4. If you join, you will have injections (of the study vaccine or placebo), blood draws and nasal swabs.
5. If you become ill with potential COVID-19, we will ask you to provide nasal samples.
6. If you take part, the most common risks are muscle aches or headaches after getting the study vaccine.
7. There are other, less serious risks. We will tell you more about them later in this consent form.

8. We do not know if getting the study vaccine will benefit you in any way.
9. Take your time to decide – you may take an unsigned copy of this form home to read again and discuss with your other doctors, family, and friends.
10. Ask the study doctor or staff your questions.

Thank you for taking the time to consider to take part in this study.

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

Thank you for reading this. You will be given a copy of this information to keep.

Patient's Name:		CRF #:	

Participant Information Sheet.

1. What is the purpose of this study?

Why is this study being done?

This study is being done to test the new experimental vaccine called Ad26.COV2.S on adolescents and adults. 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. SARS-CoV-2 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 disease such as cough and extreme tiredness, but some people have severe disease and have difficulty breathing and can even die from this disease.

General information about the study.

About 660 adolescents and 550 adult participants will take part in this study. If you join the study, you will be in it for about 19 months. During the study, we will collect blood and nasal swab samples. If you become sick with COVID-19- and as explained later, you cannot get COVID-19 from the vaccine - the study staff will monitor you regularly and ask you for additional nasal swab samples.

During the study, the sponsor may learn new information about the study vaccine such as risks. Your study doctor will tell you as soon as possible about any new information that might make you change your mind about being in the study, such as new risks. You may not benefit from

participating in this study since we do not know if the vaccine will work. There is a small chance you may have a bad reaction to the vaccine or it may make you sicker if you get COVID-19.
You may choose not to participate and will not lose any access to medical care or other benefits otherwise available to you.

2. What is the drug that is being tested?

The new experimental vaccine being tested in this study is called Ad26.COV2.S. A vaccine helps to prevent disease by allowing the human body to form an immune response against what causes the disease, such as viruses or bacteria. This defensive response is a way your body fights infections. The immune response that Ad26.COV2.S causes is specific for SARS-COV-2. This study is to help determine if Ad26.COV2.S is safe for humans and if it causes an immune response that protects against COVID-19 disease.

This study will test this experimental vaccine to help doctors and scientists learn how to prevent disease caused by SARS CoV-2. The main purpose of this study is to see:

- How well Ad26.COV2.S works to prevent COVID-19 disease
- If the Ad26.COV2.S vaccine is safe
- If it causes any side effects and what they are
- How well the vaccine is tolerated by people in the study
- What the best dose of the vaccine is

Doctors and scientists will also 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)

What is the study vaccine?

Ad26.COV2.S 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 cause an infection.

The Ad26.COV2.S study vaccine includes genetic material from SARS-CoV-2 virus. When the study vaccine is injected into your child's body, the genetic material from SARS-CoV-2 gets "translated" to produce so-called 'spike proteins' which are specific to SARS-CoV-2. Our bodies recognize these proteins and make an immune response against them. This immune response is

our body's way of fighting the infection. Your child cannot contract COVID-19 from the study vaccine.

Ad26.COV2.S is experimental, which means it is not approved for use by any Regulatory Authority in any country. Therefore, it can only be used in a research study that is approved by the sponsor, such as this one.

3. What treatment will I receive?

There are 6 adolescent treatment groups for adolescents in this study. Each study participant will be assigned to one group.

Not everyone in the study will get Ad26.COV2.S. You will either get Ad26.COV2.S or placebo. You will randomly (by chance) be put into the Ad26.COV2.S or placebo vaccine group. You have an 90% chance (600 out of the 660 adolescent participants) of getting the Ad26.COV2.S vaccine.

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

What other treatments are there outside of this study?

There are currently no approved vaccines for COVID-19. The UK Health Authorities have approved one or more COVID-19 vaccines for emergency use which will be rolled out in a phased manner in the coming months/years in order of clinical priority. There may also be other clinical studies in your area testing different potential vaccines against COVID-19. The study doctor will explain to you the benefits and risks of these other treatments. You will also receive a separate form from your study team that explains more about your options in regards to other COVID-19 vaccines outside of this study.

Early unblinding for administration of COVID-19 vaccines

The UK government is conducting national roll out of authorised COVID-19 vaccines. The vaccines will be rolled out according to the government prioritisation plan. This plan does not currently include the vaccination of adolescents, but adolescents may be invited to receive an authorised COVID-19 vaccine at some point in the future. Should you be invited to be vaccinated with an authorised vaccine, you must first be "unblinded" in this clinical trial in which you are participating. This means that you must learn whether you were given the COVID-19 vaccine or the placebo (salt water) as part of this study. The unblinding will be performed only when an authorised vaccine is rolled out in your area AND when you are eligible to receive it. At that

point, if you decide to be vaccinated with an authorised COVID-19 vaccine, the authorised vaccine would be administered by the NHS. However, we encourage you to continue to participate in this study by attending your visits as scheduled. Before you are given the authorised vaccine, your study doctor/site staff may ask you to come for an extra visit. You will also be asked to provide details of the authorised vaccine you are given and the dates you receive it.

If the vaccine candidate currently being tested in this study is authorised in the UK by the regulatory health authority, those who received placebo (salt water) in this study will be provided with the option to receive Janssen's authorised COVID-19 vaccine. This will be done in consultation with the health authority, and a protocol amendment will be prepared describing how this process will occur. The protocol amendment will require approval from local regulatory authorities.

4. Can I take the study drug after the study is over?

After you complete the trial, you will no longer receive the study drug. After the trial, a plan will be developed in accordance with local and national regulatory authorities to determine if and when it is recommended that those participants who received placebo vaccine may be vaccinated with the Ad26.COV2.S vaccine. Neither you nor your doctor will know which vaccine you were assigned until after the end of the study. As a result, placebo participants may not receive Ad26.COV2.S for at least 15 months after initial vaccination. Your study doctor or staff will discuss your future medical care options with you.

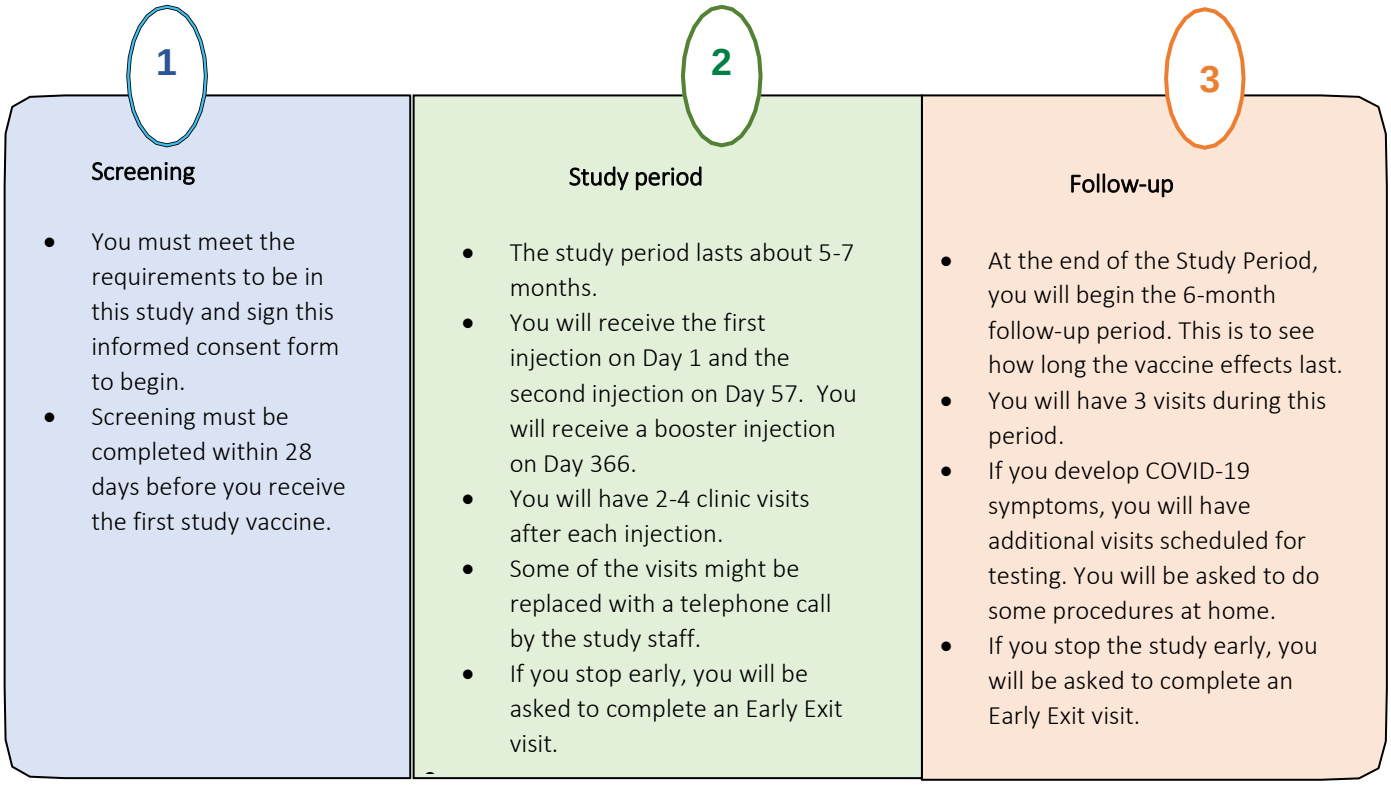
5. Do I have to take part?

Taking part in this study is voluntary. You do not have to be in this research study.

You can talk to the study doctor first before you make this decision.

6. What will happen if I take part?

The study is divided into 3 parts.



7. What is done at each visit?

Study procedures and activities

Throughout the study you may have a physical exam where we measure your height and weight, your blood pressure, heart rate, and body temperature. We will also ask you questions about your general health, medical history and medications you take.

You will be given a small machine called a pulse oximeter and a thermometer during your first study visit to take home with you.

This table describes other procedures you can expect to have during the study. Not all procedures will be done at every visit. Some procedures may not be able to be completed if you have a telemedicine visit (that is, a remote visit done by video or phone call). Some procedures may be required to be done at your home by study staff or by a home health nurse. The study doctor or study staff will discuss this with you in more detail.

Please see the Schedule of Activities tables at the end of this document to learn what procedures are done at every visit.

Procedure	What is it?
Informed Consent	The study doctor or staff will talk to you about the study and you'll decide if you want to join.
Pulse oximetry	This is measured by a small device on your finger. It is a painless test that measures the oxygen levels in your blood, and measures your heart rate.
Blood draw to test for SARS-CoV-2 specific antibodies	If available, a blood test will be done at the screening visit to identify if you have been exposed to SARS-CoV-2. If the results of your blood test indicate that you have been exposed to SARS-CoV-2, it is possible that you may not be eligible for the study.
Nasal Swab Testing	At the screening visit, a cotton swab will be inserted in your nose to collect a sample for testing. You may experience some slight discomfort or tickling in the nose while this procedure is being done. It may also cause a nosebleed. A nasal swab kit will also be given to you so that you can collect a sample 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, and when/how to return the collected sample to the study site. If necessary, your caregiver or a

	home nurse can assist you in collection of the swabs. The study site may arrange for supplies to be delivered to and/or samples collected from your home. For this purpose, they may need to share your contact information with a courier.
Review of risks and possible side effects of vaccines	At each visit, the study doctor/staff will ask about any side effects. All vaccines can cause side effects. Problems that are not expected may arise and they may be life-threatening. Potential risks are further outlined below in "What are the Possible Side Effects and Risks?" section. You will remain under observation by the study staff for 1 hour after each injection.
Vaccination	You will receive the vaccination with the randomly assigned study vaccine as described in the "What treatment will I receive?" within the STUDY VACCINE/OTHER MEDICATIONS section below. The place on your arm where you get the vaccine may have redness and become sore.
Diary	You will be given a diary (paper booklet) and an explanation of how to use it. You will report information daily, starting from the day of the study vaccine, and for the 7 days afterwards (for a total of 8 daily records). Staff will show you how to note: Daily symptoms, such as tiredness, headache, nausea, and muscle pain Pain or tenderness, redness, and swelling at the site of the injection (using a ruler at home) Your daily body temperature using a thermometer at home (you should measure your temperature at the same time each day) You must bring the diary with you to each visit.
Questionnaires	During the study period, you will be asked to complete questionnaires daily if you experience any COVID-19-like symptoms. This is done via the "daily symptom calendar". If the answer is 'Yes' for any symptom, you will need to contact the site, start to complete additional questionnaires on the development of these symptoms, and collect nasal swab samples.

	You may have a caregiver assist with completion of the questionnaires as needed.
Urine sample	If you are a female who could get pregnant, we will collect a urine sample from you to check for pregnancy.
Blood draw/tests	The study doctor or staff will draw blood from a vein in your arm. You may get a bruise or irritation at the place where the needle goes into your skin. Some participants may faint and, in rare cases, can get an infection. For adolescents, the total amount of blood that will be drawn during the entire study is approximately 180 ml (about 13 tablespoons) An additional 20 ml (about 1⅓ tablespoons) will be drawn from participants who develop COVID-19. 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: For confirmation of SARS-CoV-2 infection To check your immune response to the study vaccine The study doctor or staff will discuss with you the test results that are medically important.
Sample collection for scientific/genetic research	Any of your blood samples could be used for scientific and limited genetic research as described in the "Samples Collected for Scientific/Genetic Research" section below. You will be informed if testing on your samples for this study will change. You will be asked to confirm in the Informed Consent Form to agree for your blood samples to be used for scientific/genetic research.

Review of concomitant medications	You will talk with the study doctor or staff about any other medications you take including prescription medicines, over the counter medications, supplements, vitamins, or herbal products.
Phone calls or telemedicine visits	During the study, the study staff will contact you regularly by telephone or other means of communication to remind you of what you need to do in case you are experiencing COVID-19 symptoms. It might also be possible that certain on-site study visits will be replaced by telephone calls or home visits by study staff.

8. Expenses and Payments.

You will not be paid for taking part in this study. You will be reimbursed for those expenses directly related to the study visits such as local travel, meals and parking.

The Sponsor of this study will pay University Hospital Southampton for including you in this study.

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

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

9. What do you have to do?

Study rules

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

Overall study rules	
You must do the following:	**You must NOT do the following:**
• Give correct information about your health history and health condition • Tell the study doctor and staff about any health problems you have during the study. Note: you should contact	• Do not take part in any other medical research studies (including other COVID-19 vaccine studies) • Do not get pregnant or cause someone else to become pregnant

the study staff as soon as you start experiencing COVID-19-like symptoms. • Talk to your study doctor before getting any other licensed vaccines (such as flu vaccine). • Complete the vaccine diary and questionnaires and bring to all visits • Provide all required samples, e.g. nasal swabs and blood draws • Come to all study visits • Agree and be able to be contacted by the study staff on a regular basis	
Medicines	
You/Your child must do the following:	**You/Your child must NOT do the following:**
• Tell the study doctor and staff about any new medicine or drug you take during the study, including over-the-counter drugs (for example, to prevent or treat side effects of the study vaccine). Also tell the study doctor and staff about any changes to your medicines or drugs.	
Other	
You/Your child must do the following:	**You/Your child must NOT do the following:**
• Bring the "Patient Instructions for Hospitalisation" letter with you to the hospital if you require care at a hospital/accident and emergency department for any reason.	

What about my current medicines?

You must tell the study doctor and staff about all your prescription and over-the-counter medicines. This includes vitamins and herbs.
You may continue to take your medication(s) while you are in this study.

10. How will I receive the study vaccine?

How do I take the study drug?

If you decide that you will take part in the study, you also agree that you will take the study drug as directed by the study staff.

The study vaccine is given by injection. A needle is put into the muscle of your upper arm. You will receive the study vaccine three times during the study.

You must remain at the study site for observation for one hour after receiving the study vaccine.

11. What are the possible side effects and risks of participating?

Before participating you should consider if this will affect any insurance you have (e.g. travel insurance, protection insurance (life insurance, income protection, critical illness cover) and private medical insurance) and seek expert advice if necessary.

Risks

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/filovirus, Zika virus, HPV (Human Papillomavirus) and malaria. As of 04 September 2020, approximately 114,000 participants were vaccinated with Ad26-based vaccine in ongoing studies, 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 study 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 has been administered to 805 human participants, aged 18 and older. Following administration of Ad26.COV2.S, 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 study doctor's recommendation. Please tell the study staff if you take anything.

In a Phase 3 trial of Ad26.CoV2. S vaccine, one study 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 study team.

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, 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 infection 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. We will do this by taking nasal swabs in participants suspected of having SARS-CoV-2 infection. Study participants with a positive test result will be followed until the signs 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 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 study, please tell your study doctor 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 study 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 receive the injection
- Fever and chills
- Rash
- Itching in other areas of your body
- Aches and pains
- Muscle and joint pain
- Throwing up and nausea
- Headache
- Dizziness
- Feeling very tired
- 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.

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 one hour after each injection.

Risk of Testing Positive for SARS-CoV-2 Antibodies.

If you receive the AD26.COV2.S vaccine, your body may have an immune response to the specific coronavirus protein that is 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 speak with study staff if you need to get tested for COVID-19

outside of this study. 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.

12. What are the possible benefits of taking part?

There is no direct medical benefit to you from being in this study. But, your participation may help other children and may serve to further research of COVID-19 disease.

13. What happens if I stop the study early?

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

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

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

If you stop the study early and you withdraw your consent at any time, you agree not to limit the use of information collected about you for the purpose of the study up to the point of your consent withdrawal.

The Sponsor will continue to collect information from you as described in other sections of this Informed Consent Form (see "Samples collected for [Scientific/Genetic] Research," "Samples Used for Future Research," and "What happens if I stop the study early?"). The Sponsor will not collect any new information from you for any parts of the study from which you have withdrawn your consent.

14. Cautions.

Birth control and pregnancy during the study

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 the 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.COV.S. For this reason, in this study, we will not enroll pregnant women, or those who aim to get pregnant within 3 months of receiving the study vaccine. The appropriate animal studies 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 bilateral tubal ligation/clip (surgical sterilization) or surgical removal of both ovaries, 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 study. You will be required to agree to use an approved method of birth control (as described below) beginning 28 days prior to the first study vaccination and continuing for 3 months after the administration of last study vaccination. In addition, you will need to have a negative pregnancy test before each vaccination.

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

- Hormonal contraceptionIntrauterine devices (IUD)
- Intrauterine hormone-releasing systems
- 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 study vaccination)

Please talk to the study staff about specific questions concerning acceptable birth control methods. 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 each study vaccine administration to confirm 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 investigator 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.

15. What if something goes wrong?

If you feel that you have suffered any significant deterioration in health or well-being caused directly as a result of your participation in the study, immediately contact your study doctor. If you need treatment for a medical event or injury that happened to you as a result of study drug(s) or procedures, medical care will be provided to you.

Your doctor will make sure that you get medical care and advice during and after the study and will notify the Sponsor of any potential compensation claims.

The Sponsor will provide compensation for any injury caused by taking part in this study in accordance with the guidelines of the Association of the British Pharmaceutical Industry (ABPI). Broadly speaking the ABPI guidelines recommend that the Sponsor should compensate you without you having to prove that it is their fault or go to court.

In the event of dispute, the case may be referred to an arbitrator in accordance with the ABPI Guidelines. Your right at law to claim compensation for injury where you can prove negligence is not affected but you cannot claim compensation under the guidelines as well as at law.

The Sponsor will pay compensation where the injury probably resulted from:

- A drug being tested or administered as part of the study protocol;
- Any test or procedure you underwent as part of the study.

The Sponsor has agreed to be bound by the ABPI guidelines. (Please ask if you wish more information on this or go to the ABPI website at www.abpi.org.uk).

The Sponsor will not pay the costs to test or treat a condition or injury that is not related to the study drug or study procedure, or for expenses related to the normal progression of a pre-existing medical condition or an underlying disease. In no event will the Sponsor pay for treatment for injury or illness that is not a result of the study.

The Sponsor will maintain insurance for clinical research as required by local law and regulations.

To help avoid injury, it is very important to follow all study directions.

The above statements do not limit your legal rights.

16. What happens if I don't want to carry on with the study?

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

Please talk to your study doctor first before deciding to change your participation.

17. Can I be removed from the study?

Yes, the study doctor/staff and the study sponsor have the right to remove you from the study at any time, with or without your agreement. Removal from the study may happen if:

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

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

18. Will my taking part in this study be kept confidential?

General information on the use of personal data in research.

Health and care research should serve the public interest, which means that the Sponsor has to demonstrate that the research serves the interests of society as a whole by following the UK Policy Framework for Health and Social Care Research.

The Sponsor uses personally-identifiable information to conduct research to improve health and care. As a pharmaceutical company the Sponsor has a legitimate interest in using information relating to your health and care for research studies, when you agree to take part in a research study. This means that the Sponsor will use your data, collected in the course of the research study, in the ways needed to conduct and analyse the research study.

How will my data be used?

The Sponsor for this study is based in Europe and will use information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that the Sponsor is responsible for looking after your information and using it properly.

How will my personal data be protected?

Your personal data will be labelled 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 NHS number are included in your coded data.

Your coded data will be used to learn more about the SARS.COV2.S Vaccine. In addition, your coded data may be used:
-For submissions to regulatory authorities;
-To help with the design of future studies;
-For research, which is compatible with research related to this study including statistical purposes.

What personal data will the study staff collect?

University Hospital Southampton NHS Foundation Trust will collect information from you and/or your medical records for this research study in accordance with the Sponsor's instructions.

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

University Hospital Southampton NHS Foundation Trust will keep your name, NHS number and contact details, other identifiers, e.g. date of birth confidential and will not pass this information to the Sponsor. University Hospital Southampton NHS Foundation Trust will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from, or authorised by, the NHS, Sponsor and regulatory organisations may look at your medical and research records to check the accuracy of the research study.

The Sponsor will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

How long will my personal data be stored?
University Hospital Southampton NHS Foundation Trust will keep identifiable information about you from this study for a minimum of 15 years after the study has finished on behalf of the Sponsor. In addition, the Sponsor will retain your coded data in accordance with the regulations for research.

How will my 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 EU. With regards to transfers from the EU to other countries, including the U.S., 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.

What rights do I have concerning my personal data?

Your rights to access, change or move your information are limited, as the Sponsor needs to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, the Sponsor will keep the information about you that has already been obtained. To safeguard your rights, the Sponsor will use the minimum personally-identifiable information possible.

You can find out more about how the Sponsor uses your information by contacting the Sponsor via your study doctor or by using the email address for the Data Protection Officer given below.

If you wish to raise a complaint on how the Sponsor has handled your personal data, you can contact the Sponsor's Data Protection Officer who will investigate the matter. If you are not satisfied with the response or believe the Sponsor is processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

You can contact the Sponsor's Data Protection Officer via your study doctor or by email at emeaprivacy@its.jnj.com.

19. Remote access to your records at the study site.

Representatives of the sponsor (i.e., monitors or 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.

20. Involvement of the General Practitioner/Family Doctor (GP)

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

21. What happens to the samples collected from me?

The sponsor may use any of your samples (blood, urine and nasal swabs) collected during this study to:

- Understand how 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 the study vaccine
- To better understand the vaccines made from adenoviruses
- To develop tests for Ad26.COV2.S vaccine and SARS-CoV-2 infections.

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

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

How are my samples kept private?

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

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

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

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

Samples Used for Future Research

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

You may opt out of future use of your samples and can withdraw your consent at any time during or after the study by notifying your study doctor. If you withdraw consent for future use of your samples, your samples will be destroyed after they are no longer required for the main study. This will not affect your access to the care, medicine, and equipment you would otherwise be getting. This can be done at any time and for any reason. You will need to do this before 15 years since the study doctor/staff will discard the medical records that link your name to your study number in 15 years.

The sponsor plans to keep the samples securely in The long term storage facility is as follows:

CSM Europe sa Biorepository

Watson & Crick Hill

Rue Granbonpre 11

B-1435 Mont-Saint-Guibert

Belgium

The samples may be re-located at any time by the sponsor

22. What will happen to the results of the research study?

After all study participants have completed the study (which may be some time and samples may be sent outside of the European Economic Area (EEA).

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

23. Who is organising and funding the research?

The organiser of this study is Janssen Vaccines & Prevention B.V. (the Sponsor) and Biomedical Advanced Research and Development Authority (BARDA) who will pay University Hospital Southampton Clinical Research Facility for including you in this study.

24. Who has reviewed this study?

All clinical research is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by London - City & East Research Ethics Committee.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. In addition, it will also be available on www.clinicaltrialsregister.eu.

This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

25. Further information and contact details

If you have any questions about the study, please contact the study doctor:
Dr Katrina Cathie, Principal Investigator, 02381 204989

If you have any concerns or wish to complain, please contact:
Patient advice and liason services (PALS) by contacting 02381 206325 or by emailing complaints@uhs.nhs.uk or pals@uhs.nhs.uk.

If you have any questions about your rights as a research participant, please contact:
Dr Katrina Cathie, Principal Investigator, 02381 204989

Schedule of Activities:

Groups A to F (56-day interval [2-dose and 1- dose regimens, with booster]) – Adolescents

1.3.4. Groups A to F (56-day interval [2-dose and 1- dose regimens, with booster]) – Adolescents

Phase	Screening[a]	Study Period													
Clinic Visit #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Exit[b]
Visit Timing		Vac 1	Vac 1 + 3 d	Vac 1 + 7 d	Vac 1 + 28 d	Vac 2	Vac 2 + 7 d	Vac 2 + 28 d	Vac 1 + 6 mo	Vac 1 + 9 mo	Vac 3	Vac 3 + 7 d	Vac 3 + 28 d	Vac 3 + 6 mo	
Visit Day ±Window	-28 to 1	1	4	8±2[c]	29±3	57 -3/+7	64*±2[c]	85*±3	183±21	275±21	366±14	373*±2[c]	394*±3	548*±21	
Visit Type	Screening	Vaccine 1	Safety Phone Call[5]	Safety	Safety and Immuno	Vaccine 2	Safety	Safety and Immuno	Safety Phone Call	Safety Phone Call	Vaccine 3	Safety	Safety and Immuno	Safety and Immuno	Early Exit
Written informed consent/assent[d]	●														
Inclusion/exclusion criteria	●	●[1]													
Demographics	●														
Medical history/prestudy meds	●														
Physical examination[e]	●														
Pulse oximetry		●[1]													
Distribution of pulse oximeter[f]		●													
Vital signs[g] incl. body temperature	●	●[2]		●	●	●[2]	●	●			●[2]	●	●	●	●[4]
Nasal swab sample and test for SARS-CoV-2 RNA	●[6]	●[7]													
Serological test for anti-SARS-CoV-2 antibody	●[6] 8	●[7] (8)													
Randomization		●[1]													
Prevaccination check[h]		●[1]				●[1]					●[1]				
Urine pregnancy test[i]	●	●[1]				●[1]					●[1]				
Humoral immunity (serum), blood draw, mL		●[1] 7.5			● 7.5	●[1]10		● 10			●[1] 10		● 10	● 10	●[3]10
Cellular immunity (PBMC), blood draw, mL[j]		●[1] 20			● 20			● 20					● 20	● 20	●[3] 20
Cellular immunity (whole blood, PAXgene® tubes), mL		●[1] 2.5			●2.5										
Vaccination		●				●					●				
1-hour post-vaccination observation[k]		●				●					●				
Solicited AE recording			- Continuous-			- Continuous--					-- Continuous- -				●[4]
Unsolicited AE recording[l]			Continuous through+28 d-			Continuous through+28 d					Continuous through +28 d				●[5]
SAE recording[m]			- Continuous- -												●

Phase	Screening[a]	Study Period													
Clinic Visit #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Exit[b]
Visit Timing		Vac 1	Vac 1 + 3 d	Vac 1 + 7 d	Vac 1 + 28 d	Vac 2	Vac 2 + 7 d	Vac 2 + 28 d	Vac 1 + 6 mo	Vac 1 + 9 mo	Vac 3	Vac 3 + 7 d	Vac 3 + 28 d	Vac 3 + 6 mo	
Visit Day ±Window	-28 to 1	1	4	8±2[c]	29±3	57 -3/+7	64*±2[c]	85*±3	183±21	275±21	366±14	373*±2[c]	394*±3	548*±21	
Concomitant meds[g]			*Continuous*												●
Participant diary distribution[c]		●				●					●				
Participant diary review[c]			●	●			●					●			
COVID-19-like Symptom surveillance booklet and nasal swab kit training and distribution		●													
(Suspected) COVID-19- surveillance[6]			*Continuous*												
Approx. blood draw per day, mL: for participants in the PBMC subset. [for participants not in the PBMC subset]	8 [8]	30[f] [10[f]]			30 [10]	10 [10]		30 [10]			10 [10]		30 [10]	30 [10]	30 [10]
Approx. cumulative blood draw, mL: for participants in the PBMC subset. [for participants not in the PBMC subset]	8 [8]	38[f] [18[f]]			68 [28]	78 [38]		108 [48]			118 [58]		148 [68]	**178 [78]**	

1.3.5. Procedures for Participants With (Suspected) COVID-19 – Adults and Adolescents

Timing relative to onset of trigger	COVID-19 Day 1	COVID-19 Days 1-4	COVID-19 Days 3-8[a]	COVID-19 Day 29 ± 7d[a]	Until resolution[b]
Trigger: Participant to contact study site as soon as any signs or symptoms of possible COVID-19 occur/at time of becoming aware of positive RT-PCR test	●				
Nasal swab[c]		●[3]	●[1]		
Physical examination[d]			●	●	
Vital signs[e] including body temperature			●	●	
Humoral immunity (serum), mL			● 15 or 7.5[i]	● 15 or 7.5[i]	
RNA-seq (whole blood, PAXgene tube), mL			● 2.5	● 2.5	
Body temperature[f]		●[2]			
Symptoms of Infection with Coronavirus-19 (SIC)[g]		●[2]			
Study-site personnel to contact participant[h]		*Weekly or more frequently*			
Pulse oximetry by site staff			●		
Pulse oximetry by the participant (to be completed by the participant in the provided booklet)		*3 times a day*			

Participant Consent Form

Study Title:

Protocol title: A Randomized, Double-blind, Placebo-controlled Phase 2a Study to Evaluate a Range of Dose Levels and Vaccination Intervals of Ad26.COV2.S in Healthy Adults Aged 18 to 55 Years Inclusive and Adults Aged 65 Years and Older and to Evaluate 2 Dose Levels of Ad26.COV2.S in Healthy Adolescents Aged 12 to 17 Years Inclusive

Principal Investigator: Dr Katrina Cathie

Please read this information carefully

Dear Sir/Madam:

1. I have read and understood this information.
2. This study has been explained to me.
3. All my questions about the study, the (Ad26.COV2.S) experimental vaccine, and possible risks and side effects have been answered to my satisfaction.
4. I give permission for my doctors, other health professionals, hospitals, or labs to release information to University Hospital Southampton NHS Foundation Trust about my health for the purposes of this study. I understand this information will remain confidential.
5. I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study.
6. I understand that I will be given a signed copy of this document to keep.

Thank you for taking the time to consider taking part in this study.

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

Patient Name: _____ CRF ID: _____

Please read the following statements and put your initials in the box to show that you have read and understood them and that you agree with them.		Please initial each box
1	I confirm that I have read and understand the information sheet dated 15-Feb-2021 for the above study. I have had the opportunity to consider the information and ask questions and have had these answered satisfactorily.	
2	I understand that my involvement is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.	
3	I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from the Sponsor or authorised by the Sponsor, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
4	I have been informed that the study doctor/staff may inform my other doctors, if any, about my participation in this study, and I agree to this.	
5.	All my questions about the study, Ad26.COV2.S ,and possible risks and side effects have been answered to my satisfaction.	
6.	OPTIONAL: I agree to the use of my bloodfor future scientific research as described in section "Samples Collected for Scientific/Genetic Research," in addition to the testing required for this study. Yes ☐ No ☐ *(Please tick yes or no)*	

To be filled in by the patient

I agree to take part in the above study

Your name	**Date** (Day/Month/Year) (e.g. 01/Jan/2018)	**Signature**

To be filled in by the person obtaining consent (investigator)

I confirm that I have explained the nature, purposes and possible effects of the research study to the person whose name is printed above. They agreed to take part by signing and dating above.

Name of Investigator (or person obtaining consent if different from Investigator)	**Date** (Day/Month/Year) (e.g. 01/Jan/2018)	**Signature**

At least one **impartial** witness is mandatory when the patient, parent, or legal guardian, or legally acceptable representative is unable to read or write. An **impartial** witness must be present during the entire informed consent discussion. **An impartial witness is not required if the patient, parent, or legal guardian, or legally acceptable representative is able to read and write**.

To be filled in by the Impartial Witness (if applicable)

I confirm that the information in the consent form was accurately explained to, and apparently understood by, the patient and/or the patient's legally acceptable representative, and that consent was freely given by the patient and/or the patient's legally acceptable representative.

Name of Impartial Witness	**Date** (Day/Month/Year) (e.g. 01/Jan/2018)	**Signature**

Instructions to Study Staff

If the study doctor signing this form is not the Principal Investigator, they must be authorised to take consent on the Site Signature (Delegation) Log.

Filing instructions: 1 (copy) for patient; 1 (copy) for medical notes; 1 (original) to be filed in the Trial Centre File