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Parent/Legal Guardian Information Sheet

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

Your child is invited to be in a research 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 child's regular health care
2. Before you decide if your child may join, please read this form carefully so you know why the research is being done and what it involves
3. Take your time to decide – you may take an unsigned copy of this form home to read again and discuss with your child, family, friends, and your child's healthcare professionals (such as their pediatrician, primary care doctor, etc.)
4. Ask the study doctor and staff your questions

Thank you for taking the time to consider having your child 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 your child's participation 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 child's healthcare provider(s), family and friends

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

Child's Name:		

Parent/Legal Guardian Clinical 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 adults will take part in this study worldwide. If your child joins the study, your child will be in it for about 19 months.
Sometimes during a study, the sponsor may learn new information about the study drug, the risks, or something else. Your child's doctor/staff will tell you in a timely manner if there is any new information that might make you change your mind about your child being in the study.

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, such as this one.

3. What treatment will my child receive?

What treatment will my child receive?

There are 6 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. Your child will either get Ad26.COV2.S or placebo. Your child will randomly (by chance) be put into the Ad26.COV2.S or placebo vaccine group. Your child has an 91% chance (600 out of the 660 participants) of getting the Ad26.COV2.S vaccine.

During the study, neither you, your child, nor the study staff will know which treatment group your child is in. However, if needed for a medical emergency, the study doctor/staff can quickly find out which treatment group your child is in.

What other treatments are there outside of this study?

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. The current recommendation is that children under 16 years of age should only receive COVID-19 vaccines as part of a clinical trial. There may also be other clinical studies testing different potential vaccines against COVID-19. The study doctor will explain to you the benefits and risks of these other treatments.

There may 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 child's study team that explains more about your child's 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 your child be invited to be vaccinated with an authorised vaccine, your child must first be "unblinded" in this clinical trial in which you are participating. This means that you/your child must learn whether your child 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 your child is eligible to receive it. At that point, if you/your child decideds to be vaccinated with an authorised COVID-19 vaccine, the authorised vaccine would be administered by the NHS. However, we encourage your child to continue to participate in this study by attending your child's study visits as scheduled. Before your child is given the authorised vaccine, your child's study doctor/site staff may ask your child to come for an extra visit. You will also be asked to provide details of the authorised vaccine your child is 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 my child take the study drug after the study is over?

After your child completes the trial, they 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, your child nor your child's doctor will know which vaccine your child was 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 child's study doctor or staff will discuss your child's future medical care options with you/your child.

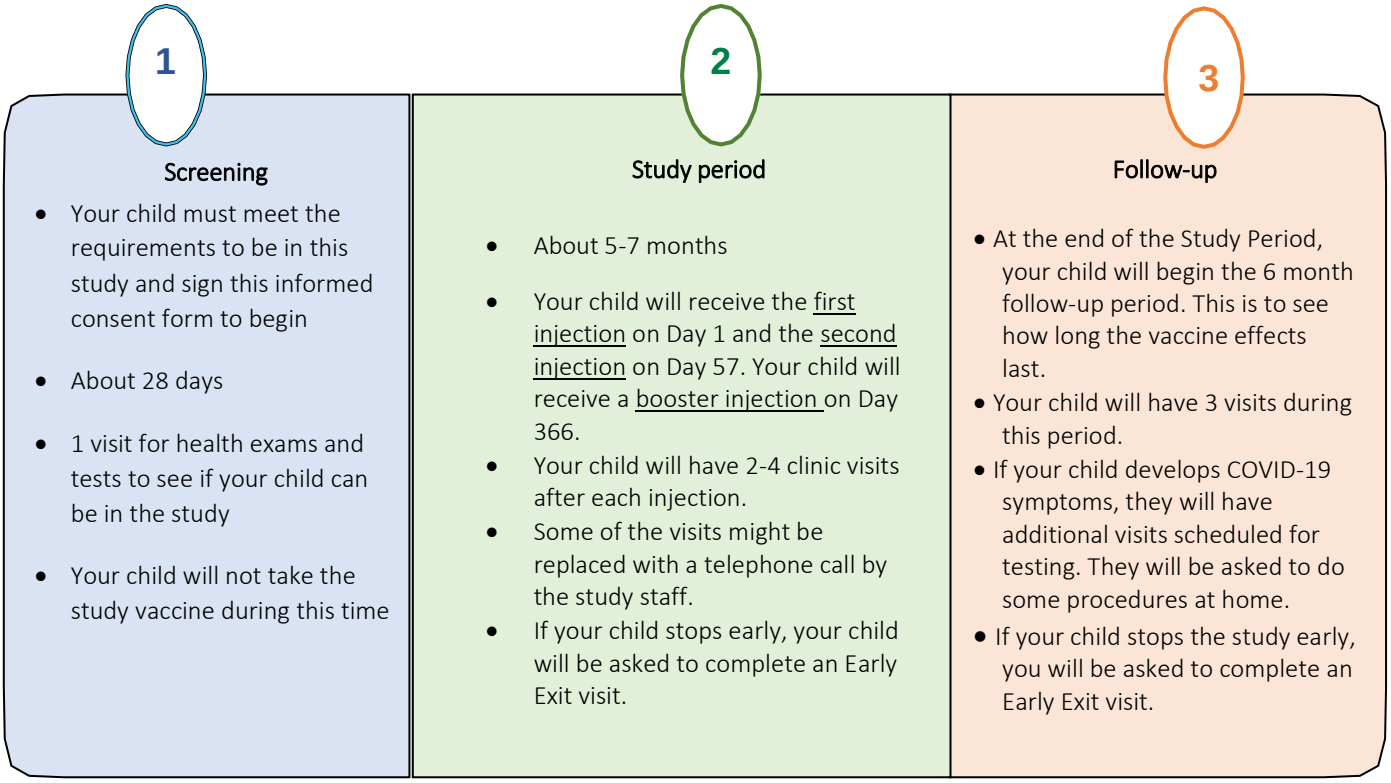
5. Does my child have to take part?

Taking part in this study is voluntary. Your child does 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 my child takes part?

The study is divided into 3 parts.



7. What is done at each visit?

Study procedures and activities

This table describes all the procedures your child can expect to have during the study. Not all procedures will be done at every visit. The study doctor/study staff will discuss this with you and your child in more detail.

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

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/staff will talk to you about the study and you will decide if you want your child to join.
Pulse oximetry	This is measured by a small device on your child's finger. It is a painless test that measures the oxygen levels in the blood, and measures the 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 your child has been exposed to SARS-CoV-2. If the results of your child's blood test indicate that they have been exposed to SARS-CoV-2, it is possible that they may not be eligible for the study.
Nasal Swab Testing	At the screening visit, a cotton swab will be inserted in your child's nose to collect a sample for testing. They 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 your child so that you/your child can collect a sample at home if they develop COVID-19-like symptoms. You/your child 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 child's caregiver or a home nurse can assist you/your child 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 child's 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. Your child will remain under observation by the study staff for 1 hour after each injection.
Vaccination	Your child will receive the vaccination with the randomly assigned study vaccine (or placebo) as described in the "What treatment will my child receive?" within the STUDY VACCINE/OTHER MEDICATIONS section below. The place on your child's arm where they get the vaccine may have redness and become sore.
Diary	Your child will be given a diary (paper booklet) and an explanation of how to use it. You/your child 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/your child 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 child's daily body temperature using a thermometer at home (you/your child should measure their temperature at the same time each day) Your child must bring the diary with them to each visit.
Questionnaires	During the study period, your child will be asked to complete questionnaires daily if they experience any COVID-19-like symptoms. This is done via the "daily symptom calendar". If the answer is 'Yes' for any symptom, you/your child will need to contact the site, start to complete additional questionnaires on the development of these symptoms, and collect nasal swab samples. Your child may have a caregiver assist with completion of the questionnaires as needed.
Urine sample	If your child is a female who could get pregnant, we will collect a urine sample from your child to check for pregnancy.
Blood draw/tests	The study doctor or staff will draw blood from a vein in your child's arm. Your child may get a bruise or irritation at the place where the needle goes into their 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. Your child may be asked to repeat a blood test if there are safety or technical issues with the initial draw. • Your child's blood will be used: o For confirmation of SARS-CoV-2 infection o To check the immune response to the study vaccine (or placebo) The study doctor or staff will discuss with your child the test results that are medically important.
Sample collection for scientific/genetic research	Any of your child's 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 child's 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/your child will talk with the study doctor or staff about any other medications they 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/your child regularly by telephone or other means of communication to remind you/your child of what you/your child need to do in case they 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.

Your child will not be asked to miss school to participate in this study and to comply with the study visits, the study Doctor/site will arrange the study visits outwith school hours.

8. Expenses and Payments.

Your child will not be paid for taking part in this study. You and your child 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 Clinical Research Facility for including your child 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 and/or your child have to do?

Study rules

For your child to participate in the study, you and your child must follow the below list of things to do and not do:

Overall study rules	
You/Your child must do the following:	**Your child must NOT do the following:**
• Give correct information about your child's health history and health condition • Tell the study doctor/staff about any health problems your child has during the study. Note: you should contact the study staff as soon as your child starts experiencing COVID-19-like symptoms. • Talk to your child's study doctor before getting any other licensed vaccines (such as flu vaccine). • Have your child complete the vaccine diary and questionnaires and bring to visits as instructed by the site. • Have your child provide all required samples, e.g. nasal swabs and blood draws • Have your child come to all study visits • Agree and be able to be contacted by the study staff on a regular basis	• Do not let your child take part in any other medical research studies (including other COVID-19 vaccine studies) • Get pregnant or cause their partner to get pregnant
Medicines	
You/Your child must do the following:	**You/Your child must NOT do the following:**
• Tell the study doctor/staff about any new medicine or drug your child takes 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 child's medicines or drugs	
Other	
You/Your child must do the following:	You/Your child must NOT do the following:
• Bring the "Patient Instructions for Hospitalization" letter with you to the hospital/accident and emergency department if your child requires care at a hospital for any reason.	

What about my child's current medicines?

You must tell the study doctor about all prescription and over-the-counter drugs your child is taking. This includes vitamins, herbs, and other kinds of therapies.

Your child will continue to take their medication(s) while they are in this study.

10. How will my child receive the study vaccine?

How does my child take the study drug?

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

The study drug is given by injection. The needle is put into a muscle in your child's upper arm. This will be done three times during the study.

Your child 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 for your child (e.g. travel insurance, private medical insurance) and seek 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 your child takes a fever reducer or pain reliever if symptoms appear after receiving the vaccination, or upon your child's study doctor's recommendation. Please tell the study staff if your child takes 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 your child develops symptoms like severe and/or persistent headache, confusion or blurred vision, you/your child should promptly notify your child's healthcare provider and/or study team.

Some vaccines may cause a more severe course of disease when your child is 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 your child has any side effects or problems during this study, please tell your child's 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/your child.

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

Your child 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 your child for one hour after each injection.

Risk of Testing Positive for SARS-CoV-2 Antibodies

If your child receives the AD26.COV2.S vaccine, their 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 child's nose or from your child's throat as these tests tell you if your child currently has COVID-19 virus in their body. Some tests, however, are done to check if your child has previously been infected with COVID-19—these tests check for antibodies. These antibody test results might be positive if your child received the AD26.COV2.S vaccine, even if your child was never truly infected with the virus. For this reason, we recommend that you/your child speak with study staff if your child needs to get tested for COVID-19 outside of this study. The study staff will provide you/your child with additional information and help your child get the right test.

If your child becomes 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 child's 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 your child 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 my child stops the study early?

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

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

If your child has side effects from the study vaccine or study procedures after they stop the study early, the study doctor/staff may contact your child's other doctors who your child sees regularly. By signing this consent form, you agree that this information can be obtained and added to your child's study record unless you indicate otherwise.

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

The Sponsor will continue to collect information from you/your child 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 your child for any parts of the study from which you have withdrawn your consent for your child.

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 your child is premenarchal (has not started menstruation/had their period), postmenopausal for at least one year or has had a total hysterectomy (surgical removal of the womb) or bilateral tubal ligation/clip (surgical sterilization) or surgical removal of both ovaries, they cannot get pregnant.Therefore, the section about contraceptive use does not apply to them.

Female Participants Who Can Get Pregnant

If your child is female and can get pregnant (meaning that they are neitherpremenarchal [has not started menstruation/had their period], postmenopausal for at least one year or has had a total hysterectomy [surgical removal of the womb] or bilateral tubal ligation/clip [surgical sterilization] or surgical removal of both ovaries) and sexually active, your child must avoid getting pregnant in order to take part in this study. Your child 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, your child will need to have a negative pregnancy test before each vaccination.

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

- Hormonal contraception
- Intrauterine 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 your child uses before they can enter the study.

If your child is a female who can get pregnant, your child must agree to have a urine β-hCG pregnancy test at screening and immediately prior to each study vaccine administration to confirm that they are not pregnant.

If you/your child suspects that they have become pregnant during the study, you/your child must notify your child's study doctor immediately. If your child becomes pregnant during the study, your child will not receive any further vaccinations. However, your child may continue in other study procedures (your child may have blood drawn for safety and immune response testing), if the investigator decides it is safe for your child and their unborn child. The study doctor will collect information about your child's pregnancy and the health of their baby. If your child does not wish to be followed, your child can withdraw their consent at any time by informing your child's doctor.

Male Participants

For male subjects, their partner must not become pregnant during the study. Inform your son's partner about this.
If your child's partner becomes pregnant during the study, you/your child should tell the study doctor immediately. Your child's 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 child's partner does not have to provide any information.

15. What if something goes wrong?

If you feel that your child has been injured or has become ill as a result of your child's participation in the study, immediately contact your child's study doctor. If your child needs treatment for a medical event or injury that happened as a result of study drug(s) or procedures, medical care will be provided to your child.

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

The Sponsor will provide compensation for 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 your child without you having to prove that it is their fault or go to court.

The Sponsor will pay compensation where the injury is serious and persistent and probably resulted from:

- A drug being tested or administered as part of the study protocol;
- Any test or procedure your child received as part of the study that your child would not have undergone but for taking part in 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 complaints procedure of the hospital where the trial is being conducted is also available to you and your child.

The above statements do not limit your child's legal rights.

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

You can agree to your child being in the study now and change your mind later at any time and for any reason. You can withdraw your child from some parts of the study or the entire study. Your decision will not affect your child's regular care. Taking part in this study is voluntary. Your child does not have to be in this research study.

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

17. Can my child be removed from the study?

Yes. The study doctor and the study sponsor have the right to take your child out of the study at any time, with or without your or your child's agreement. They will decide this if:

- It is in your child's best medical interest to stop
- Your child does not follow the study staff's instructions
- The study is cancelled
- Your child no longer meets the eligibility criteria for being in the study

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

18. Will my child's 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 child's health and care for research studies, when you agree to your child taking part in a research study. This means that the Sponsor will use your child's data, collected in the course of the research study, in the ways needed to conduct and analyse the research study.

How will my child's data be used?

The Sponsor of this study is based in Europe and will use information from your child and/or your child's 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 child's information and using it properly.

How will my child's personal data be protected?

Your child's personal data will be labelled with the study number and your child's subject number ("Your child's 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 child's coded data. Your child's coded data will be used to learn more about the how Ad26.COV2.S and similar medicines work in the body and better understand COVID-19 and associated health problems and to develop diagnostic tests.

In addition, your child's 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?

The NHS will collect information from [your child and/or your child's medical records] for this research study in accordance with the Sponsor's instructions.
The NHS will keep your child's name, NHS number and contact details, date of birth and potentially other identifiers confidential and will not pass this information to the Sponsor. The NHS will use this information as needed, to contact you and your child about the research study, and make sure that relevant information about the study is recorded for your child's 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 child's 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 your child and will not be able to find out your child's name, NHS number or contact details.

How long will my child's personal data be stored?

The NHS will keep identifiable information about your child 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 child's coded data in accordance with the regulations for research.

How will my child's coded data be shared and transferred?

The Sponsor may share your child's coded data with its affiliates and 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 child's information and to permit the compliant cross-border transfer of your child's coded data. You may contact your child's study doctor to request a copy of these measures.

What rights do I have concerning my child's personal data?

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

You can find out more about how the Sponsor uses your child's information by contacting the Sponsor via your child's 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 child's 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 child's 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 child's study doctor or by email at emeaprivacy@its.jnj.com.

19. Remote access to your child's records at the study site.

Representatives of the sponsor (i.e., monitors or auditors) may use an electronic tool to access your child's 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/staff may let your child's regular doctors know that your child is in this study and may report any side effects. It is important for your child's other doctors to know that your child is taking a study drug.

21. What will happen to any samples my child gives?

The sponsor may use any of your child's 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.

Scientists may use your child's 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 child's medical care. They will not be used to make a diagnosis about your child's health. Therefore, these results will not be given to you, your child or the study doctor/staff.

Your child's collected samples will continue to be analyzed as described in this form unless you specifically ask for your child's 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 will be stored for future use (up to 15 years). Testing will depend on the available technology at the time of testing. Additionally, your child's samples could be used for future COVID-19 (or other respiratory viral diseases) vaccine research.

You or your child have the option to opt out of future use of your child's samples and can withdraw your consent at any time during or after the study by notifying your child's study doctor. If you withdraw consent for future use of your child's samples, your child's samples will be destroyed after they are no longer required. This will not affect your child's access to the care, medicine, and equipment your child would otherwise be getting.

You (or your child once they reach age 16) will need to do this within 15 years of finishing the study since the study doctor/staff may discard the medical records that link your name to your study number after 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 and samples may be sent outside of the European Economic Area (EEA).

How are my child's samples kept private?

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

Your child's samples may be sent to other members of the Johnson & Johnson group of companies, to contractors working for them and to regulatory authorities.

Your child's samples may also be shared with research partners for scientific research purposes. Your child's samples will not be sold, loaned or given to any other independent groups for their own use. Research

partners working with the sponsor are not allowed to share samples with anyone who is not authorized by the sponsor. The sponsor will manage what is done with your child's samples.

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

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

After all study participants have completed the study (which may be some time after your child has completed their participation in the study), the Sponsor will analyze the data and offer you and your child 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 your child or any other study participant. The summary may be made available to you through a study participant web portal which you can choose to access or through certain local and/or national websites.

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

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 your child 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 child's 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 your child. 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, Principle 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 child's rights as a research patient, please contact:
Dr Katrina Cathie, Principle Investigator, 02381 204989

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[a]			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[c]			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*			

Parent/Legal Guardian 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

Child's name:		CRF ID:	
Parent/Legal Guardian's name:			

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 child's involvement is voluntary and that I am free to withdraw my child at any time, without giving any reason and without my child's medical care or legal rights being affected.	
3	I understand that relevant sections of any of my child's 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 child taking part in this research. I give permission for these individuals to have access to my child's records.	

4	I agree to my child's GP being informed of my child's participation in the study.	
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 child's blood for future scientific research as described in section "Samples Collected for Scientific/Genetic Research," in addition to the testing required for this study.	

To be filled in by the parent/legal guardian

I agree for my child to take part in the above research 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 for their child 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

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 parent/legal guardian
- 1 (copy) for medical notes
- 1 (original) to be filed in the Trial Centre File