APPENDIX 7: PRINTED (in person) INFORMED CONSENT FORM TEMPLATE

ENSEMBLE OPEN LABEL: Sisonke (Together)

Open-label, single-arm phase 3B implementation study to monitor the effectiveness of the single dose Ad26.COV2.S COVID-19 vaccine among health care workers in South Africa

CLINICAL TRIAL SPONSORED BY

South African Medical Research Council (SAMRC)

STUDY PRODUCTS PROVIDED BY

Janssen Vaccines & Prevention B.V., a Janssen pharmaceutical company of Johnson & Johnson (J&J)

INFORMED CONSENT

Why is this open-label study being done?

The J&J COVID-19 vaccine, Ad26.COV2.S, is being administered under study conditions while the regulatory processes are underway in South Africa. A single-dose regimen of this vaccine has been shown to be 57% effective overall in South Africa and 85% effective overall in preventing severe disease by Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2). This vaccine also demonstrated complete protection against COVID-19-related hospitalisation and deaths as from 28 days after receiving the vaccine.
The vaccine, although protective against severe disease and hospitalisation in all regions of the world, was found to have less impact on other milder forms of disease because of new circulating virus variants, such as 501Y.V2 in South Africa. Because of this, we will be following you up to evaluate this further.

You will receive a single injection of the Ad26.COV2.S vaccine.

General Information the COVID-19 vaccine

If you agree to participate in this open-label study you will receive a single injection of the vaccine and we will follow you up by reviewing your medical records and laboratory results for up to 2 years.

Already more than 43,000 participants around the world have participated in research to evaluate the safety and efficacy of this vaccine.

You cannot get COVID-19 from the vaccine.

You may choose to not participate in this study, in which case you will not lose access to any other medical care or other benefits already available to you.

This study is funded by the SAMRC, the National Department of Health (NDoH) .

WHAT HAPPENS IN THIS OPEN LABEL STUDY?

The study is divided into 3 parts: 1) Scheduling your visits 2) Vaccination Period, 3) Follow-Up Period.

Some participants will have extra tests and procedures

There will be a sub-set of participants that will have extra tests and procedures.
We will tell you if you are included in this group. If you are part of the sub-group being followed up at 3 and 6 months, we will collect a nasal swab to see if you have COVID-19 if you become symptomatic and blood samples (2-3 teaspoons) at 3 and 6 months from you to evaluate your immune response to the vaccine.

STUDY RESPONSIBILITIES

To participate in the study, you have responsibilities.

Overall	
Do	**Do not**
• Give correct information about your health history and health condition. • Tell the study staff about any health problems you have.	• Consult before you take part in any other medical research studies .

What is the Ad26.COV2.S study vaccine?

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

The Ad26.COV2.S study vaccine includes genetic material from the SARS-CoV-2 virus. When the study vaccine is injected into your body, the genetic material from SARS-CoV-2 gets “translated” to produce so called ‘spike proteins’ which are small bits of protein specific to SARS-CoV-2. Our bodies then make an immune response against these spike proteins. This immune response is our body’s way of fighting the infection. You cannot contract COVID-19 from the study vaccine.

J&J is filing for the emergency use of the single dose of the Ad26COV2.S vaccine in various regions of the world, including South Africa. This study is being conducted while these processes are ongoing in attempt to offer this as an emergency to health care workers.

How is the vaccine given?

The study vaccine is given by injection. The needle is put into the muscle in your upper arm. When possible, the injection will be given in the arm you use less.
You will remain at the study site for observation for about 15 minutes after receiving the vaccine.
There are currently no registered vaccines for COVID-19 in South Africa. There may be other studies in your area testing different vaccines against COVID-19.

WHAT ARE THE POSSIBLE SIDE EFFECTS AND RISKS OF PARTICIPATING?

Potential Discomforts, Side Effects, and Risks Associated with Ad26.COV2.S

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, Ad26-based vaccines have been administered to approximately 114,000 participants in ongoing and completed studies, including more than 99,000 participants in an ongoing Ebola vaccine study in the Democratic Republic of the Congo and in an ongoing immunization campaign in Rwanda. 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.
The Ad26.COV2.S has been studied in the test tube and in animals with no vaccine-related adverse effects observed. As of 2nd Feb 2021, a single injection of Ad26.COV2.S has been administered to at least 20,800 participants, aged 18 and older. Following administration of Ad26.COV2.S, fever, 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 such as paracetamol if symptoms appear after receiving the vaccination, or upon your study doctor's recommendation.
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 let the research site know immediately.
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 vaccinations can cause:

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

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

These side effects usually last 2 to 3 days.

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

Allergic reactions

You could have an allergic reaction to a vaccine, including a rash, hives, or difficulty breathing. Some allergic reactions can be life-threatening. The study staff will watch you for at least 15 minutes after each injection. Always tell the study staff if you have ever had a bad reaction to any injection or vaccine. They can give you medicines in the clinic to treat serious allergic reactions. If you think you're having a severe allergic reaction after you leave the study site, contact the emergency number and get medical help right away. Let the research site know if this occurs.

Risk of testing positive for SARS-CoV-2 antibodies

By receiving the Ad26.COV2.S vaccine, your body may have an immune response to the specific coronavirus proteins that are part of the vaccine. This immune response will not affect any results of COVID-19 tests, whether taken as part of the study or outside of the study, that are obtained from a swab of your nose (or from your throat) as these tests tell you if you currently have COVID-19 virus in your body. Some tests, however, are done to check if you have previously been infected with COVID-19—these tests check for antibodies. These antibody test results might be positive if you received the Ad26.COV2.S vaccine, even if you were never truly infected with the virus. For this reason, we recommend that you not seek testing outside of this study, but rather speak with study staff if you need to get tested. The study staff will provide you with additional information and help you get the right test.

If you become pregnant during or after the study and have antibodies in response to the vaccine, we don't know if the antibodies can be passed to your baby. We do know that antibodies from other vaccines, like tetanus vaccine, do get passed to the baby. For most babies, antibodies passed from the mother last for about six months.

Other potential risks

Blood draws may cause pain, tenderness, bruising, bleeding, dizziness, vasovagal response,

Syncope, and rarely, infection at the site where the blood is taken. Collection of a nasal swab sample may cause a nosebleed.

Benefits of Study Participation

You will receive access to an emergency use of this vaccine while we are awaiting regulatory approval. The single-dose Ad26.COV2.S vaccine regimen has been shown to be 57% effective overall in South Africa and 85% effective overall in preventing severe disease by Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2). This vaccine also demonstrated complete protection against COVID-19-related hospitalisation and deaths as from 28 days after receiving the vaccine.
You can choose to wait until the South African Health Products Regulatory Authority (SAHPRA) approves it for general use.

Participants may benefit from additional health information and clinical care.

COMMON QUESTIONS ABOUT JOINING THE STUDY

What are the costs of participating?

There are no costs to you to be in the study. The Sponsor will pay for the study vaccine and the tests that are part of the study.

Can I change my mind about participating?

Yes. You can agree to be in the study now and change your mind at any time and for any reason. Your decision will not change any regular care that you receive from this clinic. Please talk to your study doctor before changing your mind about participation.

What if I get COVID-19 during the study?

You should contact the study staff if you have COVID disease. In addition we will be undertaking passive surveillance to monitor hospitals for vaccinees who may become ill. If you are admitted or see a doctor please inform them that you are on this study. If you are one of the subset of 10 000 people who are having more intensive follow up, we will ask you at 3 and 6 months what your experiences have been.

Can I take another vaccine after getting the Ad26 COVID-19 vaccine?

If you take another COVID-19 vaccine after receiving this one, please let your doctor know. We ask that you discuss with the study staff if you are considering receiving another COVID-19 vaccine.

What do I do if I have questions or problems?

If you have questions about this study or any problems that you think may be related to this study, contact the study staff during business hours on Tel: (011) XXX.

The 24-hour telephone number is XXX.

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 then delivered animal babies. Therefore, ongoing studies with the Ebola vaccine allow pregnant women and women planning to become pregnant to receive that vaccine. While we understand more about this we would ask you about your pregnancy status at the vaccination visit. We would not vaccinate you if you are known to be pregnant.

If you suspect that you have become pregnant during the study, we ask you to notify your study doctor immediately. If you become pregnant during the study, but 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. It is considered safe to breastfeed during this study.

REIMBURSEMENT

There is no cost or reimbursement for you to be in this study. However, you will receive access to an emergency use of the Ad26.COV2.S vaccine while we are awaiting regulatory approval.

EMERGENCY CARE AND HOSPITALISATION:

If you seek emergency care or if hospitalisation is required at any time during the study or up to 24 month/s after receiving this vaccine, please tell the treating doctor that you are/were enrolled in this research study and that study staff must be informed.

ETHICAL APPROVAL

This clinical study protocol has been submitted to the University of the Witwatersrand, Human Research Ethics Committee (Wits HREC – Medical) and written approval has been granted by that Committee. The study has been structured in accordance with the Declaration of Helsinki (last updated: October 2013) which deals with the recommendations guiding doctors in biomedical research involving human participants. A copy may be obtained from me should you wish to review it.
If you have any additional questions about your rights as a research participant, you should contact the XXXXXXX) who are overseeing the conduct of this study at this clinical research centre. An Ethics Committee is an independent committee established to help protect the rights of research subjects.
{name of HREC chair, Address and Telephone number}

REGULATORY APPROVAL

If you have questions about this study you should first discuss them with your doctor or the Ethics Committee. If you have not been provided with answers to your satisfaction, you

should write to the South African Health Products Regulatory Authority (SAHPRA) who provides regulatory approval for the study at:

The Chief Executive Officer
South African Health Products Regulatory Authority
Department of Health
Private Bag X828
PRETORIA
0001
E-mail: Boitumelo.Semete@sahpra.org.za
Tel: (012) 501 0410

SAMPLES COLLECTED FOR SCIENTIFIC RESEARCH

What happens to the samples collected from me if I am one of the subset?

The Sponsor may use any of your samples collected during this study to

- Understand how the Ad26.COV2.S vaccine works, or why it may cause side effects
- To better understand COVID-19 disease
- To test if you may be infected with other respiratory viruses such as influenza (flu).
- Understand why people may respond differently to the study vaccine
- To better understand 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.
To protect your privacy, your samples will be labelled 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 or given to any other groups for their use. Researchers working with the Sponsor are not allowed to share samples with anyone who is not authorized by the Sponsor.
You will not be paid for any use of your samples or results, or for 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 analysed 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

Any samples remaining after they are used for the main study will be stored for future use for 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 research on future COVID-19 vaccines or other respiratory viral disease vaccines.
You may opt out of future use of your samples or withdraw your consent at any time 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.
The Study Staff and the Sponsor will manage your personal data (information about you) in compliance with [insert reference to applicable law on data protection and privacy] as described in this consent form.

What personal data will the study staff collect?

If you join this study, the study staff will collect and use your personal data that may include information about your health.

- Demographic information such as your name, your study ID #, home address, e-mail address, telephone/mobile number, date of birth, and gender which will be entered into the Vaccine Register
- Contact information about your emergency contact; and caregiver, if applicable
- The name of your regular doctor and the hospital where you would likely seek care if you become seriously ill with COVID-19
- Sensitive information about your physical or mental health or condition
- Information from any forms you are asked to complete

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How will your personal data be protected?

All information obtained during the course of this study, including hospital records, personal data and research data will be kept strictly confidential. Data that may be reported in scientific journals will not include any information that identifies you as a participant in this study.
Any information uncovered regarding your test results or state of health as a result of your participation in this study will be held in strict confidence. You will be informed of any finding of importance to your health or continued participation in this study, but this information will not be disclosed to any third party in addition to the ones mentioned above without your written permission. The only exception to this rule will be cases of communicable diseases where a legal duty of notification of the Department of Health exists. In this case, you will be informed of our intent to disclose such information to the authorised state agency.
The South African National Clinical Trials Register provides the public with updated information on clinical trials on human participants being conducted in South Africa. The Register provides you with information on a trials purpose; who can participate, where the trial is located, and contact details. No information identifying participants is available. You can access this information at www.sanctr.gov.za at any time.

How will Data be used by the Sponsor?

Your Data is needed for the Sponsor to learn about Ad26.COV2.S, get permission to introduce and keep it on the market, monitor its safety and get it covered by health

insurances and health service providers. Therefore, they will be used as planned in this study as well as within related research activities in order to:

- understand how Ad26.COV2.S works in the body
- better understand COVID-19 and associated health problems
- develop diagnostic tests
- learn from past studies to plan new studies or improve scientific analysis methods
- publish research results in scientific journals or use them for educational purposes.

How will Your Coded Data be shared and transferred by the Sponsor?

The Sponsor may share Your Coded Data with its affiliates, health and regulatory authorities, ethics committees, authorized service providers and, with select investigators and scientists conducting scientific research, that is compatible with research related to this study including statistical purposes. Your Coded Data may also be shared with scientific journals so the study results can be reviewed by independent scientists and to ensure the accuracy of results. Your identity will not be revealed in any of these cases. These data will be utilised by them only in connection with carrying out their obligations relating to this clinical study. The Sponsor will protect Your Coded Data as far as the law allows and will keep and supervise the information collected about you only for as long as needed.

Sharing of your anonymized data by the Sponsor

Anonymized means your data and samples will be stripped of your participant number as well as of any other information that could identify you. The anonymized data and samples may be shared only for scientific research as allowed by law.

How long will your personal data be stored by the Sponsor?

Records containing your personal data will be retained at the study site for a period of [insert retention period as per local requirements]. In addition, the Sponsor will retain Your Coded Data for time periods as allowed per applicable laws for the identified use.

What rights do you have concerning your personal data?

If you would like to review, correct, delete, or make other requests about your personal data, you should contact your study doctor at [insert contact details].
You may not be able to review some of the data until after the end of the study and a request to delete your personal data cannot be fulfilled where regulations and laws that apply to clinical research require your personal data to be retained.
You can ask your study doctor to send any questions, concerns or complaints you may have to the Sponsor.

GENERAL STUDY INFORMATION

Who do I contact for information?

If you have any questions about the study, please contact:
[Insert appropriate study site personnel name, phone number, and title]

If you feel that this study has caused you any harm, please contact:
[Insert Investigator name, phone number, and title]

If you have any questions about your rights as a research participant, please contact the study doctor/staff or:
[Insert IRB or IEC name and phone number]

YOUR AGREEMENT TO PARTICIPATE

If you agree to join the study, please read and then sign below.

- I have read and understood this information.
- This study has been explained to me.
- All my questions about the study, the Ad26.COV2.S experimental vaccine, and possible risks and benefits have been answered to my satisfaction.
- I give permission for my personal information to be collected from national and other laboratories as well as other approved data sources and kept in the Sponsor's database and understand that any data shared and used for the study as explained in this consent form will be Coded Data (anonymized).
- I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study.
- I understand that I will be given a signed copy of this document to keep.
- If a caregiver is required, I consent to allow my designated caregiver to provide support with my study related activities.

I have been informed that the study doctor/staff may inform my regular doctors (if any) about my participation in this study, and I agree to this. (You may still be in this study even if you do not agree to this.)

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

For the SUBSET participants only: I agree to the use of my samples for future scientific research as described in section "Samples Collected for Scientific Research".

Yes ☐ No ☐

_____
Printed name and surname of participant in full

_____
Signature of participant Date (dd/mmm/yyyy)

For participants who are unable to read or write, a witness should complete the signature block below:

Printed name and surname of witness in full

Signature of witness Date (dd/mmm/yyyy)

Printed name and surname of person obtaining consent

Signature of person obtaining consent Date (dd/mmm/yyyy)