



**MASTER TEMPLATE**  
**Participant Information Sheet**

## Sisonke Phase 3b open label Clinical Trial

Each **participant** must read and understand this document **before** any study-related procedures.

**Sisonke:** Open-label, single-arm phase 3B implementation study to monitor the effectiveness of the single shot Ad26.COVS COVID-19 vaccine among health care workers in South Africa.

To monitor the effectiveness of the single shot Ad26.COVS COVID-19 vaccine among health care workers (HCW) in South Africa

**Investigator:** Dr Nivashnee Naicker

**Institution Site:** CAPRISA eThekweni CRS

**Contact number (24 HRS):** 082 413 4694

### We are inviting you to take part in a research study called SISONKE (Together)

South Africa is severely affected by the global COVID-19 epidemic, but currently no vaccine has been rolled out. The recent promising results of the 'ENSEMBLE' trial conducted by Janssen in South Africa, and the availability of a limited amount of vaccine doses, provide the rationale for

a cohort study of vaccinated HCWs to inform the larger vaccine rollout.

- Please take time to read the following information carefully. Discuss it with friends and relatives if you wish. Take time to decide whether or not you wish to take part.
- You are free to decide whether or not to take part in this research study. If you choose not to take part, this will not affect the care you get from your own doctors in any way.
- You can stop taking part in the study at any time, without giving a reason.
- Ask us if there is anything that is not clear or if you would like more information.
- Thank you for reading this information. If you decide to take part in the study, you will be asked to consent to take part.

### Important things that you need to know

- We want to find out two things:
  - The reduction in known COVID infections in vaccinated health care workers
  - the effectiveness of the vaccine to prevent severe disease and death:
- This is an open label study: that means everyone in this study will receive a single shot of the Ad26.COVS COVID19 vaccine.
- Like all vaccines, the COVID vaccine used in this study, can have unwanted side effects. The most common side effect is that the injection site may be red, swollen and feel sore for a day or two.

- The study will fit into your normal schedule, so for most people, there are no hospital visits. In a small subset of HCWs only, you will need to give a nasal or nasopharyngeal swab and a small blood sample before you start, at three months and at the end of the study at six months.

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## 1 Why are we doing this study?

This study is carried out to see the effectiveness of Ad26 Covid Vaccine to prevent or reduce the severity of COVID-19 in healthcare workers.

### What is COVID-19?

A new coronavirus pandemic is sweeping the world and is called COVID-19. This is caused by infection with a virus called SARS-CoV-2. The illness is usually mild, but it can cause a severe chest infection (pneumonia) or death in some people. If you want to know more about COVID-19, please look at the World Health Organisation (WHO) website:

<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/>

### How is COVID-19 usually prevented?

Although some drugs reduce the severity of COVID-19 in hospital patients, vaccines are just being licensed in some parts of the world and this is the first roll out of vaccines in South Africa. Physical distancing, quarantine and infection control measures are the only interventions currently available here in South Africa.

### What are we trying to find out?

We want to find out two things:

- Whether we see less COVID infection in health care workers who have been vaccinated.
- Whether healthcare workers who do get infected experience a milder disease if they have received the Ad26 vaccine.

## 2 Why am I being asked to take part?

You are being asked to take part in the Sisonke study because you are a healthcare worker who may be at high risk of being exposed to COVID-19 and may therefore catch the disease.

### Do I have to take part?

No, joining the study is voluntary; it is up to you to decide whether or not to take part. If you decide to take part, you will be given this information sheet to keep and you will be asked to consent to the study.

A decision to not take part will not be held against you and will not affect the standard of care you receive if you become ill at any time.

## 3 What do I need to know about the vaccine used in this study?

The Jansen 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. The Ad26.COVID.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.COVID.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 Ad26COVID.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

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## 4 What will I need to do if I take part?

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This is an open-label single arm study. That means that you will receive a single shot of the Ad26 vaccine. You must be aged 18 years or older, have registered on the national vaccine site, and be willing to attend one of the vaccination centres or research sites to be vaccinated. We would also require your permission to collect hospital and laboratory data.

### **Can I definitely take part?**

Not everyone will be able to take part in this study. We need you to answer some questions first.

Women who are pregnant, or those who intend to get pregnant within one month of entering the trial, will be advised to defer.

You will be asked to inform the research staff:

- If you have received another vaccination in the previous 30 days.

You will also need to agree to allow access to your healthcare records to 1) confirm medical data if necessary, or 2) if you are admitted to hospital during the study or become ill so we can collect study follow up information.

### **What if I am immunocompromised or living with HIV?**

- If you are uncertain of your HIV status or have not had an HIV test within the past 12 months we would encourage you to test for HIV before joining this study. While Ad26 vaccine is safe for people living with HIV who are not severely immunocompromised, it is important that you know your status prior to joining this trial. If you need information about where you can get tested for HIV, we will provide you with this information.

### **What if I have allergies?**

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 on the vaccination card and get medical help right away.

### **What if the questions show I can take part?**

Before you can enter the study, you will need to complete a questionnaire about your health to make sure that this study is suitable for you.

If your answers to the questions show you can take part and you agree to join the Sisonkestudy, we will ask you to sign an online consent form. A member of the study team will contact you to confirm your identity, suitability to take part and that you understand and agree to the conditions of the study.

### **What will happen to me during the**

## **study?**

Once your suitability in the study is confirmed by the local investigator, and you have signed the eConsent you will be given the vaccination. Data will be collected using routine data sources from the National Department of Health by linking your ID/passport national number, name and other locator information for up to 2 years after receiving the vaccination. If you develop COVID-19 and want to take part in a treatment study, you can do it, but we would like you to inform the study team to ensure your safety and best possible care. We may check your medical and laboratory records if we are alerted to possible breakthrough COVID infection.

In a subset of volunteer HCWs we will draw a small sample of blood to COVID19 exposure at the time of vaccination and at 3 and 6 months. At that time we will check on your health status and repeat the blood test to rule out COVID-19 infection at this time, and again at 6 months. At the end of the study we may check your medical and laboratory records.

### **What checks and tests will be done?**

During the study, if you develop symptoms of COVID19, including cough, shortness of breath or difficulty breathing, fever, chills, muscle pains, sore throat, or new loss of taste or smell we advise you to follow the NICD guidance. You can also ask your health care provider to assist with sample collection.

### **Interim Analyses**

We will be analysing the information we receive regularly throughout the study. If there is clear evidence that the risks outweigh the benefits, we will stop the study early.

### **Will I get paid to take part?**

There is no reimbursement for this study.

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## **5 What are the possible side-effects?**

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### **What are the most common side-effects?**

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 this vaccine. These reactions usually start within 1 to 2 days after

the injection and most of the reactions get better within 1 to 3 days.

### **Are there serious side-effects?**

It is rare for anyone to have a serious allergic reaction to a vaccine. If this does happen, it usually happens within minutes. The person who vaccinates you will be trained to deal with allergic reactions and treat them immediately. With fast treatment you will make a good recovery.

Vaccines similar to Ad26.COVS.2 (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.

The Ad26.COVS.2 has been studied in the test tube and in animals with no vaccine-related adverse effects observed. As of 2<sup>nd</sup> Feb 2021, a single injection of Ad26.COVS.2 has been administered to at least 20,800 participants, aged 18 and older. Following administration of Ad26.COVS.2, 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 if symptoms appear after receiving the vaccination, or upon your study doctor's recommendation.

There may be risks associated with Ad26.COVS.2 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.

If you become concerned about any side-effects, please tell the study staff as soon as possible.

### **Pregnancy and Breast Feeding**

Animal studies have shown that Janssen's licensed Ad26-based vaccine against Ebola did not raise concerns in preclinical reproductive

toxicity studies. These are studies in pregnant animals that received the vaccine, and then delivered animal babies. Therefore, ongoing studies with the Ebola vaccine allow pregnant women and women planning to become pregnant to receive that vaccine. 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 within 3 months of receiving the vaccine, please notify the number of your vaccination card. If you do not wish to be followed, you can withdraw your consent at any time by informing your doctor.

The vaccine is safe to use in women who are breastfeeding for both mother and baby.

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## **6** What are the possible benefits of taking part in this study?

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The information we get from this study will help us understand COVID vaccines and their effectiveness in South Africa.

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.

You may benefit from the health information that you receive as a result of being part of the study.

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## **7** What are the possible disadvantages and risks of taking part?

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There are no disadvantages to taking part in this study. Whilst there is a small risk of study participation disclosure this is small since where possible data will be anonymised before reporting.

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## **8** More information about taking part

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### **Who is organising and funding the study?**

The study is funded by the SA MRC and National Dept of Health. The vaccines have been donated by Johnson and Johnson.

The principal investigators (PI) are not receiving any money or other payment for asking you to be part. As local representative of the international sponsor, the Wits Health Consortium (WHC) has overall responsibility for the conduct of the study in South Africa. The WHC is responsible for ensuring the study is carried out ethically and in the best interests of the study participants.

### **What are your choices about how your information is used?**

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

A decision to stop taking part at any time will not affect the standard of care you receive if you become ill.

If you agree to take part in the sub study, you will have the option to take part in future research using your data saved from this study. If you do, we will separately request informed consent for this.

### **How will we use information about you?**

We may need to use information from your medical records, your hospital and/or your

healthcare provider/laboratory for this research study. This information will include where appropriate, your ID number, name, date of birth, postcode, contact details and healthcare information related to this study. We are not allowed to gather information about you that does not directly inform this study. People will use this information to do the research or to check our records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Some of your information will be shared with researchers from other countries from across the world. This includes researchers from countries taking part in the study as well as those who might request use of your anonymous study information after the study is complete.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

### **What will happen to the results of the Sisonke study?**

When the study is completed, we will publish a summary of the results.

We will also publish the results in a medical journal, so that other doctors can see them. You can ask the study team for a copy of any publication. Your identity and any personal details will be kept confidential. No named information about you will be published in any report of this study.

### **Who has reviewed the Sisonke study?**

The study has been reviewed by international scientists. It has been approved by all relevant Clinical research committees and written approval has been granted by those committee.

It has been authorised by the South African Health Products Regulatory Authority (SAHPRA). These groups have been involved in the planning

and preparation of the study and will not have access to your information.

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 the PI if you wish to review it.

### **What if new information becomes available during the course of the study?**

Sometimes during a study, new information becomes available about the vaccines that are being studied. If this happens, the research team will tell you about it.

### **What happens if the Sisonke study stops early?**

Very occasionally a study is stopped early. If it happens, the reasons will be explained to you.

### **What if something goes wrong for me?**

If you become ill with COVID19 you will be referred to a COVID19 hospital for care. Please tell your treating doctor that you are enrolled in this trial. Your treating doctor can contact the local investigator on the numbers below for more information about the trial.

Every care will be taken in the course of this clinical trial. However, in the unlikely event that you are injured by taking part, compensation may be available.

The SA MRC will provide compensation for reasonable medical expenses incurred as a result of study-related injury or illness, or death determined according to the guidelines laid down by the Association of the British Pharmaceutical Industry (ABPI Compensation Guidelines Version 2014), and Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa.

[http://www.abpi.org.uk/media/1607/compensation\\_guidelines\\_2014.pdf](http://www.abpi.org.uk/media/1607/compensation_guidelines_2014.pdf)

Please notify the investigator immediately of any complications, side effects and/or injuries during the study and the nature of the expenses to be covered.

If a research related injury occurs, you have not waived any of the legal rights which you

otherwise would have as a participant in this study by signing this form.

The insurance does not cover medical treatment of other injuries or illnesses or injury caused by non-observance of the protocol.

The investigator is indemnified conditional on compliance with the protocol, SAHPRA and University of KwaZulu Natal Biomedical Research Ethics Committee and is not a substitute for medical malpractice insurance.

Please note that if you have a life insurance policy you should enquire whether your insurance company requires notification of your intention to participate in a clinical study. Information to date is that it should not affect any life insurance policy taken out. Nevertheless, you are strongly advised to clarify it with the company concerned.

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## 9 Contacts for further information

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If you want further information about the Sisonke study, contact:

Investigator: Dr Nivashnee Naicker  
Institution: CAPRISA eThekweni CRS  
Contact Number: 031 655 0618  
Email: Nivashnee.Naicker@caprisa.org

More information is also available on our website [www.crowncoronation.com](http://www.crowncoronation.com).

If you have any concerns about the way you have been approached or treated during the study, please talk to the principal investigator whose name and details are on this document.

If you are still unhappy, or if you want information regarding your rights as a research participant, or complaints regarding this research study, you may contact

University of KwaZulu Natal Biomedical Research Ethics Committee, Professor D R Wassenaar via email at [brec@ukzn.ac.za](mailto:brec@ukzn.ac.za) or by calling during office hours on 031 260 4495.

After you have consulted your doctor or the ethics committee and if they have not provided you with the answers to your satisfaction, you should write to the South African Health Products Regulatory Authority (SAHPRA):

*The Chief Executive Officer  
South African Health Products Regulatory Authority (SAHPRA)  
Department of Health  
Private Bag X828  
Pretoria, 0001  
E-mail: [Boitumelo.Semete@sahpra.org.za](mailto:Boitumelo.Semete@sahpra.org.za)  
Tel: 012 842 7629/26*

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

