Sisonke Heterologous mRNA-1273 boost after prime with Ad26.COV2.S (SHERPA study)

Participants Information and Consent Form

An Open-label, phase 3 study to evaluate the effectiveness of heterologous mRNA-1273 boosting of the single or two dose Ad26.COV2.S COVID-19 vaccine among health care workers in South Africa

Study name: Sisonke 4 (SHERPA)

Study number: Sisonke 4 (SHERPA)/ mRNA-1273-P508

Study Sponsor: South African Medical Research Council (SAMRC)

Study Doctor (Investigator): Prof Glenda Gray

Dear Health Care Worker and Sisonke participant,

<u>You are invited to take part in this research study.</u>

Before you agree to take part in this research study, please read this document carefully.

Before you continue reading this document, here are a few key things for you to know:

- Joining this research study is voluntary. It is your choice to participate or not.
- Joining this study is not part of your regular health care.
- If you join, your participation in this study will last for about 12 months.
- If you join, you will be vaccinated against COVID-19 with a booster dose
- You will have an additional blood draw and nasal swab, and other laboratory tests if you agree to take part in the sub-study.
- You may take an unsigned copy of this form home to re-read and discuss with your doctor/s, family, and friends
- You may ask the study doctor and site staff any questions**.**
- You may choose to not participate in this study, in which case you will not lose access to any medical care or other benefits already available to you.
- Take your time to decide.

Thank you for taking the time to consider this study.

WHY IS THIS PHASE 3 OPEN-LABEL STUDY BEING CONDUCTED?

Since the global pandemic of COVID-19 started in 2019 many people have become sick and many have died. Nevertheless, the response was fast and two highly effective SARS-CoV-2 mRNA vaccines were developed against the spike (S) protein of the ancestral strain of the virus originally circulating in Wuhan (Wuhan-Hu-1, D614). These are the so-called Pfizer-BioNTech BNT162b2 mRNA vaccine and the Moderna mRNA-1273 vaccine. Both vaccines were approved or authorized for emergency use in the United States and other countries, leading to expanded access and widespread use. In addition, there are several other vaccines against SARS-CoV-2 being used worldwide that use other, non-mRNA technologies such as adenovirus vector vaccines, inactivated virus vaccines, and subunit vaccines.

Evidence from clinical trials and real-world effectiveness studies have shown that these mRNA vaccines effectively prevent symptomatic disease among adults and children. More recently, data has shown that a third dose of mRNA vaccines generates good immune responses (so-called neutralizing antibody and T cell responses) against variants of concern of the virus, including against Omicron. Therefore, several countries like the US, Israel and European countries have opted to offer their populations mRNA booster doses. As primary vaccination levels are still not high enough in many low- and middle-income countries, discussions on boosters were somewhat delayed. Nevertheless, South Africa has decided to move forward with offering boosters as of 2022.

Considering good safety and immunogenicity data from heterologous mRNA boost studies, the Sisonke 4 (SHERPA) study provides the ideal opportunity to test mRNA boosting with the 50 microgram (µg) Moderna mRNA-1273 vaccine after a single or two doses of Ad26.COV2.S among health care workers in South Africa and also provide SAHPRA, the South African regulator, with local data on the safety and effectiveness to support potential licensure of this vaccine in South Africa.

If you agree to participate in this open-label study, you will receive a single injection of the mRNA-1273 vaccine, and there is no placebo in the study. We will then follow you up by reviewing your vaccination and medical records and laboratory results for up to 2 years.

More than 43,000 participants around the world have already participated in research to evaluate the safety and efficacy of this vaccine. A further 7 million have participated in the post licensure roll out of this vaccine, and many more have received the vaccine around the world during vaccination programmes. The effectiveness of the mRNA-1273 vaccine in the setting of immune suppression is not known.

Please note, that **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 South African Medical Research Council (SAMRC) and the manufacturer of the vaccine, Moderna, Inc. The study sponsor is the SAMRC, and the study will be conducted in collaboration with the National Department of Health (NDoH).

WHAT HAPPENS IN THIS OPEN LABEL STUDY?

If you decide to join this study, you will have a screening and enrollment visit. This could be done as one or split into two visits. At screening we will check whether you understand the study or if you have any questions and take your consent to join the study.

We will then briefly ask you questions about your general health, your vaccination history, whether you take any medications. We will also briefly examine you. If you are female of reproductive age, we may also ask you to do a pregnancy test. In case you are pregnant, that would not exclude you from the study, but we would follow you up carefully. We will next take a blood sample (up to 1 teaspoon) from you to check for previous COVID-19 infection and a nasal swab to check whether you carry the virus at the time of your visit. Once that is done you will have the mRNA-1273 Moderna vaccine booster administered, and you will be observed by study staff for approximately 15 minutes. If all is well, you will then complete the visit and get reimbursed. Once you had your booster, you are good to go, and you will only have to return to the site if you have any issues. We will monitor you through the study safety desk and will send you a text message with a link where you can report any issues. No additional visits are required, except if you join the sub-study.

WHAT WILL HAPPEN IF I JOIN THE SUB-STUDY?

Approximately 200 participants will be enrolled into the safety and immunogenicity sub-study to check on your immune response. Those who enroll into the sub-study will have extra tests and procedures. After providing written consent, participants will be enrolled at designated research sites. Participants will have a clinical assessment done including a pregnancy test to assess eligibility. Once eligibility has been confirmed baseline immunogenicity bloods will be drawn (approximately 50ml or up to three and a half tablespoons) before the booster vaccine will be administered. Post-vaccination, participants will be observed for a minimum of 15 minutes. Participants in the safety sub-study will be reviewed after 4 weeks and 24 weeks to check participants for any safety issues, called adverse events. Blood samples will be collected from the sub-study participants at enrolment, week 4 and week 24 to assess immune responses to the booster vaccine. In addition, nasal swabs will be collected for SARS CoV-2 PCR testing at all visits.

At clinical research sites that take part in the safety sub-study, all pregnant women enrolled in SHERPA will be offered participation into the sub-study. Pregnant women will only have 8ml (less than 1 tablespoon) of blood drawn. If a participant is breastfeeding, we may also ask you to provide some breastmilk (approximately 60ml or 4 tablespoons) so that we can check the immune responses in the milk.

WHO MAY PARTICIPATE?

You may participate if:

- you are 18 years or older
- you are already a Sisonke participant
    - you received at least one Ad26.CoV2.S vaccination as part of the Sisonke study OR
    - you received a second dose of Ad26.CoV2.S vaccine as part of the Sisonke 2 study and this was administered at least 3 months ago
- If you are pregnant or breastfeeding at the time of enrolment you can join the study.
- you are willing and able to comply with the vaccination plan and other study procedures.
- you are capable and willing to provide informed consent

You may NOT participate

- If you have received any COVID-19 vaccines other than one or two doses of Ad26.CoV2.S through other means (for example, another mRNA booster dose).
- If you are currently participating in any other research studies (other than Sisonke) that would interfere with the objectives of this study.
- If you have had COVID-19 or a COVID-19 illness within 14 days of enrolment
- If you have a history of heparin-induced thrombocytopenia, or thrombosis and thrombocytopenia syndrome.
- If you have a history of severe adverse reaction associated with a vaccine and/or severe allergic reaction (e.g., anaphylaxis) to any component of mRNA-1273.
- If you report a pregnancy which began prior to or within 30 days after you received a second dose of Ad26.CoV2.S and the pregnancy is ongoing at the time of enrolment.
- If you have any significant acute or chronic medical condition, situation or circumstance that in the opinion of the PI/designee makes you unsuitable for participation in the study or jeopardises your safety or rights.

STUDY RESPONSIBILITIES

To participate in the study, you have some responsibilities:

- Give correct information about your health history and health condition.
- Tell the study staff about any health problems you have.
- Report any side effects or health problems that may occur for 24 months post enrolment.

WHAT IS THE MRNA-1273 STUDY VACCINE?

The mRNA-1273 COVID-19 vaccine was developed and manufactured by the company Moderna. The vaccine consists of a messenger ribonucleic acid (mRNA) that encodes for the S protein of SARS-CoV-2, a protein that the virus uses to attach to our cells in the nose, throat and lung. The mRNA is covered by a lipid layer that allows the mRNA to enter a cell and thereby trigger the process to make the S protein. Your immune system will then recognize the S protein and start mount an immune response.

This vaccine has been approved for use by the US Food and Drug Administration and by the European Commission for active immunization to prevent COVID-19 caused by SARS-CoV-2 virus in individuals 18 years and older. The vaccine has also been granted Emergency Use Listing by the World Health Organization but has not been formally licensed by the SAHPRA, the South African regulator for active immunization to prevent COVID-19, yet.

HOW IS THE VACCINE GIVEN?

The mRNA-1273 vaccine will be administered to you as a single dose 0.25 mL suspension of 50 µg booster dose. 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.

WHAT ARE THE POSSIBLE SIDE EFFECTS AND RISKS OF PARTICIPATING?

Potential Discomforts, Side Effects, and Risks Associated with the Moderna mRNA-1273 Covid-19 Vaccine

In general, this mRNA-1273 vaccine has been safe and well tolerated. To date, millions of people have already received the study vaccine. In clinical trials, most people who got the study vaccine had some reaction after their injections. In most people the reaction to the study vaccine did not affect their daily lives and it went away after 2 or 3 days. Most of these people said they had pain in the arm where they got the injection. These people also felt tired, had headaches, muscle and joint pain, and chills. A much smaller number of these people said they had redness or swelling where the needle went in their arm. Some people also said they had nausea, fever, and swelling or pain in their arm pit. Some people also experienced underarm gland swelling on the side of study vaccination.

A small number of people who got the study vaccine had myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart). The chance of having this occur is very low. It was seen more often in people, mostly men, less than 30 years of age. Symptoms began within a few days after getting the vaccination. It did not last long, and most people got better. You should tell us right away if you have chest pain, shortness of breath, or the feeling of a fast-beating, fluttering, or pounding heart, as you may need medical care.

The side effects of the study vaccine seen so far are the same as what have been seen with most vaccines. Generally, vaccines can cause fever, chills, rash, aches and pains, nausea, headache, dizziness, and feeling tired. Vaccines can also cause pain, redness, swelling, or itching where you got the injection. Most people can still do their planned activities after getting a vaccine. Rarely, people have side effects that limit their normal activities or make them go to the doctor.

There may be other risks that we don't yet know about, even serious ones. We will tell you if we learn about any new risks.

Allergic reactions

You could have an allergic reaction to this vaccine, including a rash, hives, or difficulty breathing. This is very rare. 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 may 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.

If you develop any severe symptoms, we advise that you seek care urgently, advise your doctor that you have recently been vaccinated and ask them to contact the **Sisonke safety desk on 0800 014 956.**

There may be other risks associated with mRNA-1273 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.

You will receive an SMS on the day of vaccination, and on day 7, day 14 and 28 after vaccination, with messaging on common signs and symptoms to look out for after receiving the mRNA-1273 vaccine. Selected participants may receive additional SMSs between day 7-10, if required. This SMS will include a link to report any health concerns to the Sisonke Safety desk. Remember, you can call the Sisonke Safety desk at any time.

All vaccines can cause side effects. Problems that are not expected may happen and these may be important. If you have any side effects or problems during this study, please let the research site or the study Sisonke Safety desk know immediately and seek care at your nearest health care facility.

An overall review of adverse reactions reported following the mRNA-1273 heterologous booster dose (Johnson and Johnson vaccine followed by the Moderna vaccine) did not identify any new safety concerns, as compared with adverse reactions reported following the mRNA-1273 vaccine primary series doses or homologous booster dose.

Risk of testing positive for SARS-CoV-2 infection

By receiving the mRNA-1273 vaccine, your body may have an immune response to the specific coronavirus proteins that are part of the vaccine. This immune response should 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.

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.

WHAT ARE THE POTENTIAL BENEFITS OF STUDY PARTICIPATION?

You will receive the mRNA-1273 booster vaccine, which has been shown to be one of the most potent vaccine boosters, and has already been licensed for emergency use in many countries. This may prevent you from getting COVID-19, and in the event that you get COVID-19 infection, it may prevent you from getting very sick, needing to go to hospital or even dying.

Participants may benefit from additional health information and clinical care as part of the study and may enjoy being part of an important research study, that could lead to greater access of this vaccine.

COMMON QUESTIONS ABOUT JOINING THE STUDY

What are the costs of participating?

There are no financial costs to you to be in the study. The SAMRC and Moderna will supply the 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 number below /on the vaccination card if you have COVID-19 disease. In addition, we will monitor hospitals in South Africa for vaccinees who may become ill. If you are admitted or see a doctor, please inform them that you are on the Sisonke 4 (SHERPA) Study.

Can I take another vaccine after getting the mRNA-1273 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. The vaccine should protect you for at least 3 months, but probably longer, so there is no immediate need to get 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 on site telephone number XXX during business hours or the Sisonke Safety Desk at: **0800 014 956.**

WHAT IF I AM PREGNANT OR BREASTFEEDING DURING THE STUDY?
Both the mRNA-1273 Moderna vaccine and the J&J/Janssen COVID-19 vaccine that you received previously have been found to be safe in pregnancy and during breast feeding. The mRNA-1273 vaccine has been used widely including pregnant women with no concerns. It is therefore considered highly unlikely that the vaccine would be harmful if administered in pregnancy or during breastfeeding.

If you are pregnant or breastfeeding we will monitor you more closely after your vaccination. If available at your site, you can enrol into the sub-study. Otherwise, our safety team will be in regular contact with you to enquire about any side effects for you or your baby (if you are breastfeeding). The study team will also stay in touch with you until after your delivery to ensure all is well with you and your baby.

If you suspect that you have become pregnant during the study, we ask you to notify the Study team or the Sisonke Safety Desk immediately.

What if I get sick?

If you become ill, please seek health care and please inform your doctor/nurse that you are enrolled in the study. Your treating doctor or you can contact the numbers below for more information.

Every care will be taken during the study, but if in the unlikely event you are injured by taking part, compensation may be available.

SAMRC insurance 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) http://www.abpi.org.uk/media/1607/compensation_guidelines_2014.pdf, 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

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 related research committees, 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 study like this. 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.

REIMBURSEMENT
Participants will be reimbursed an amount of R350 for each completed.

Screening and enrolment into the study may be completed in one visit. If the screening and enrolment visit is completed on the same day, you will receive R600.

Participants who enrol into the sub-study component will receive R350 for each completed follow up visit at the Week 4 and Week 24 timepoints.

This amount is to cover the costs of transportation to and from the clinic, inconvenience, refreshments and time spent in the clinic.

You do not have to pay anything to be in this study.

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 the Sisonke Study and the SHERPA study, and that the Sisonke Safety Desk should be informed. The number for the Sisonke Safety Desk is: **0800 014 956.**
The Sisonke Safety Desk will retrieve medical records, including laboratory and imaging reports for all participants in order to complete the regulatory requirements to report all serious adverse events and adverse events of special interest to SAHPRA and Ethics Committees.

ETHICAL APPROVAL
This clinical study protocol has been submitted to the South African Medical Research Council Ethics Committee 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 South African Medical Research Council Human Research Ethics Committee who is 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.

Ms. Adri Labuschagne
SAMRC Ethics Committee
P.O. Box 19070
Tygerberg, Cape Town
Tel: 0219380687
Fax: 0866854023
E-mail: adri.labuschagne@mrc.ac.za

REGULATORY APPROVAL

If you have questions about this study you should first discuss them with the Clinical Research Site team, or the Sisonke Safety Desk, or the related 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 enrolled into the sub-study for more in-depth evaluation?

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

- Understand how the mRNA-1273 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 develop tests for mRNA-1273 vaccine and SARS-CoV-2 infections.

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) and the scientists doing the research will not know your identity.

Your samples may be sent to the Sponsor and other members of the Moderna 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 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 South African regulations 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 number, 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
- Information about your physical or mental health or condition
- Information from any forms you are asked to complete

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 Study Staff and the Sponsor will manage your personal data (information about you) in compliance with Protection of Personal Information (POPI) Act as described in this consent form.

How will Data be used by the Sponsor?
Your data is needed for the Sponsor to learn about the mRNA-1273 vaccine, monitor its safety effectiveness. Therefore, they will be used as planned in this study as well as within related research activities in order to:

- understand how mRNA-1273 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, monitors or auditors, 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. A description of this study will be available on ClinicalTrials.gov. and the South African National Clinical Trial Registry (SANCTR) These websites will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time

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 personal data will be retained for at least 10 years after closure of the study by the Sponsor. 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:
The Principal Investigator on XXXX or the **Safety desk: 0800 014 956** or the Sisonke website at: http://sisonke.samrc.ac.za

If you feel that this study has caused you any harm, please contact:
Sisonke Safety desk: 0800 014 956

If you have any questions about your rights as a research participant, please contact the study doctor/staff on XXXX or:
SAMRC Human Research Ethics Committee on 0219380687

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 mRNA-1273 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 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.

Participation in the Sisonke 4 (SHERPA)/ mRNA-1273-P508
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:

Yes	No
☐	☐

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 SUBSTUDY participants only:
I freely agree to participate in this substudy as described and understand that I am free to withdraw at any time during the study:

Yes	No
☐	☐

I agree to the use of my samples for future scientific research as described in section “Samples Collected for Scientific Research”:

Yes	No	Not applicable, not participating in the substudy
☐	☐	☐

_____
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)