



Sisonke eConsent - Enrolment Portal User Manual

v7 - 25 February 2021

National Department of Health EVDS SMS Notifications

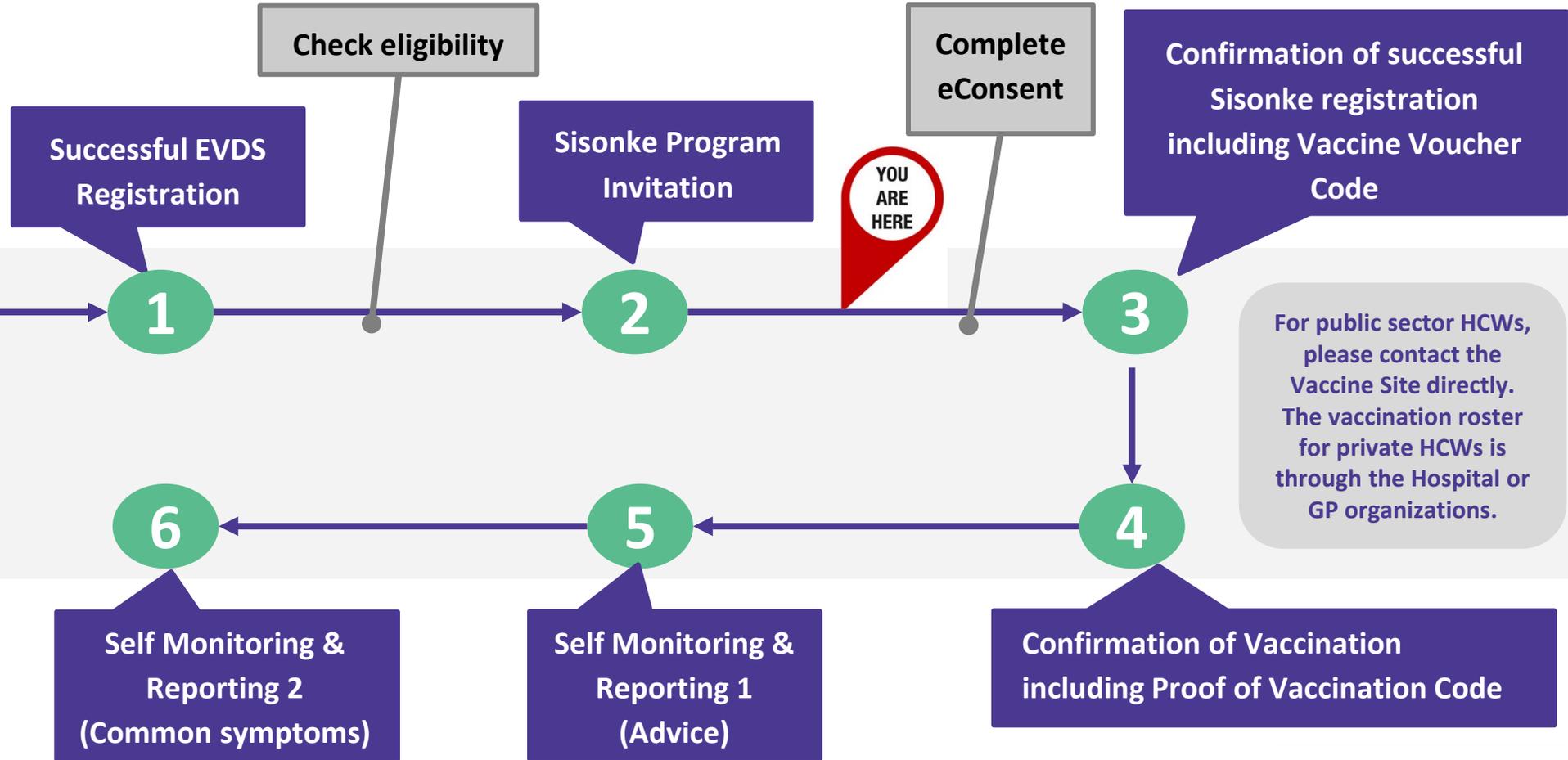
PREREQUISITE

SISONKE

National Department of Health Electronic Vaccination Data System (EVDS) Self Registration

REGISTER

vaccine.enroll.health.gov.za



sisonke.samrc.ac.za



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

Please follow the weblink: https://is.gd/sisonke_ae to report illness (including symptoms of or confirmed COVID-19) and/or contact the Sisonke Safety-Desk: 0800-014-956.



Who is eligible to enrol for the Sisonke Vaccine Program?

Eligible Healthcare Workers who receive an **invitation SMS** after enrolling on the Electronic Vaccination Data System (EVDS) Self Registration System at vaccine.enroll.health.gov.za



Dear [Name] Thank you for registering for the National Vaccine roll out. The SAMRC and NDoH are offering HCWs to access the J&J Sisonke Vaccine Program. This vaccine is a safe and effective single-dose vaccine. To proceed and give consent, go to <http://sisonke.samrc.ac.za/> Once you have consented a Vaccination Voucher will be issued for you to attend the closest Vaccine Site.



sisonke.samrc.ac.za

Summary of SMSes a Sisonke vaccinee will receive

| SMS | STEP | SMS TEXT |
|-----|--|--|
| 1 | <p>Successful EVDS Registration</p>  | <p>Dear [Name] you have successfully registered on the National Department of Health Electronic Vaccine Data System on [Date]. You will be contacted via SMS regarding next steps.</p> <p>OR Dear [PERSON] you have been registered on the National Department of Health Electronic Vaccine Data System by [Organisation, e.g. Life Healthcare] on [Data e.g. 14-Feb-2021]. Contact your Data Administrator for more information.</p> <p><i>If you do not receive one of these, please ensure you have registered on the National Department of Health EVDS self registration system at vaccine.enroll.health.za</i></p> |
| 2 | <p>Sisonke Program Invitation</p>  | <p>Dear [Name] Thank you for registering for the National Vaccine roll out. The SAMRC and NDoH are offering HCWs to access the J&J Sisonke Vaccine Program. This vaccine is a safe and effective single-dose vaccine. To proceed and give consent, go to http://sisonke.samrc.ac.za/ Once you have consented a Vaccination Voucher will be issued for you to attend the closest Vaccine Site.</p> <p><i>If you do not receive this (after having registered on the EVDS) it means you are currently not eligible for the Sisonke Program. As soon as this changes you will automatically receive an invitation by SMS, and your ID/Passport will be known to the Sisonke Program.</i></p> |

Summary of SMSes a Sisonke vaccinee will receive

| SMS | STEP | SMS TEXT |
|-----|---|---|
| 3 | <p>Confirmation of successful Sisonke registration</p>  | <p>Dear [Name], you have successfully enrolled into the Sisonke Vaccine Program. We look forward to welcoming you at [Site Name]. Your voucher number is [Voucher Number]. This Voucher along with your ID document/passport is required at the Vaccination Site. For public sector HCWs, please contact the Vaccine Site directly. The vaccination roster for private HCWs is through the Hospital or GP organizations.</p> <p><i>If you do not receive this you have not completed the eConsent process.</i></p> <p>Once you receive your voucher you can proceed to the vaccination process. Note: The vaccinator will ask you additional health related questions that may still preclude you from proceeding with vaccination.</p> |
| 4 | <p>Confirmation of Vaccination</p>  | <p>Dear [Name], you have received your vaccine on [DD/MM/YY] at [Site Name]. Your Proof of Vaccination Code is [Vaccination Proof Code]. Please keep this code in a safe place, should you be required to verify your vaccination status.</p> <p>This is the SMS you will receive after your vaccination is completed. There may be a delay, depending on the operational processes followed on-site.</p> |

Summary of SMSes a Sisonke vaccinee will receive

| SMS | STEP | SMS TEXT |
|-----|--|---|
| 5 | Self-Monitoring and Reporting 1/2  | <p>Your wellbeing is of importance to us. Continue to practice social distancing, wearing a mask and other preventive measures even after receiving a COVID-19 vaccine. Please follow the weblink: https://is.gd/sisonke_ae to report illness (including symptoms of or confirmed COVID-19) and/or contact the Sisonke Safety-Desk: 0800-014-956.</p> <p>This SMS will be received shortly after vaccination is completed.</p> |
| 6 | Self-Monitoring and Reporting 2/2 | <p>Common symptoms after vaccination include pain, swelling and redness at the injection site, fever, headache, tiredness and other flu-like symptoms may occur. These symptoms usually last 1-2 days. Should these persist, please follow the weblink: https://is.gd/sisonke_ae to report illness (including symptoms of or confirmed COVID-19) and/or contact the Sisonke Safety-Desk: 0800-014-956.</p> <p>This SMS will be received shortly after vaccination is completed.</p> |

What do you need to submit your eConsent for Sisonke?

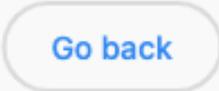
If you receive the invitation SMS, you need the following to apply:

- **Access to the internet** on any device (cellphone, laptop, tablet, desktop etc.)
- Your ID number or Passport (non-RSA), general contact information (**your cellphone number will be used as the primary mode of communication**).
- With all information at hand registration should take approximately **2-3 minutes**.

1

General Instructions

- Use 'Go Back' to return to the previous page
- Use 'Next Step' to proceed
- Use your **backspace button to delete** and replace entries
- **All questions are compulsory and only 'Yes' responses will allow you to proceed to the next screen.**
- Please complete in **one sitting, as your information will not be saved until you finish** the registration.

A blue button with rounded corners and a white border, containing the text "Go back" in blue.A blue button with rounded corners and a white border, containing the text "Next step" in blue.

Sisonke Electronic Consent Portal Landing Page

Sisonke Electronic Consent Portal



Before you proceed please download the Sisonke Participant Information Leaflet and Additional Information from the link below.

Please read these documents carefully as you will be required to answer questions about them on the next screens in order to proceed with enrollment.

[Download Sisonke Participant Information Leaflet & Info](#)

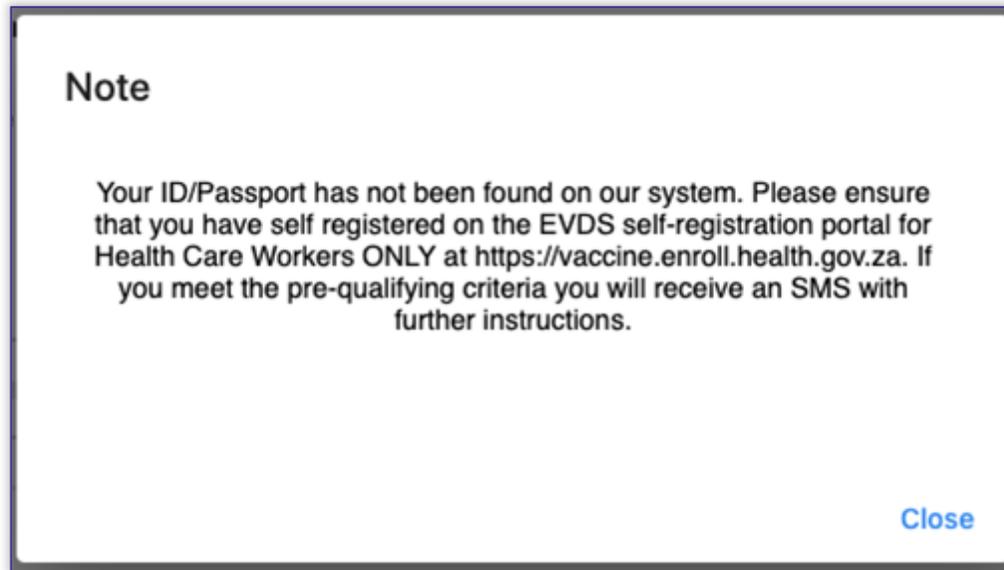
Once you have received your SMS of invitation (SMS #2), please complete the eConsent Process.

Please type in your **RSA ID number** OR Non-RSA Passport that you used on your EVDS self-registration.

***Note:** The system will only authorise eligible individuals to proceed (those who received an SMS invitation **SMS #2**), by checking your ID/Passport.

2

Sisonke Prompt to self-enrol on EVDS as prerequisite



Should you receive this prompt, it means you have **not received an invitation to participate, and the eConsent portal will not accept your ID or Passport.**

If you have already enrolled on the Self Registration Portal, this means you are currently ineligible.

vaccine.enroll.health.gov.za

Download Sisonke Information Sheet

Please click the '**Download Sisonke Participant Information Leaflet & Info**' button to **download and read the documents.**

Before you proceed please download the Sisonke Participant Information Leaflet and Additional Information from the link below.

Please read these documents carefully as you will be required to answer questions about them on the next screens in order to proceed with enrollment.

[Download Sisonke Participant Information Leaflet & Info](#)

PATIENT INFORMATION LEAFLET (ENGLISH)

Sisonke Phase 3B open label Program

(VAC1518COV3012)

Each participant must read and understand this document **before** consenting to join.

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

To monitor the effectiveness of the single dose Ad26.COV2.S COVID-19 vaccine among health care workers (HCW) in South Africa.

Sponsor: South African Medical Research Council
Francie van Zijl Drive, Parowvallei, Cape Town;
7505 Tygerberg, South Africa

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 vaccination program of 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 program. If you choose not to take part, this will not affect the care you get from your own doctors in any way.

Important things that you need to know

- We want to find out two things:
 - the effectiveness of the vaccine to prevent severe disease and death from COVID19 in health care workers
 - The reduction in COVID infections in vaccinated health care workers
- This is an open label study: that means everyone in this program will receive a single dose of the Ad26.COV2S 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 (approx. 10 000), you will need to give a nasal or nasopharyngeal swab and a small blood sample before you start, at three months and at six months.
- You will be in the program for 2 years.

Contents

- Why are we doing this program?
- Why am I being asked to take part?
- What do I need to know about the vaccine used in this program?
- What will I need to do if I take part?
- What are the possible side-effects?
- What are the possible benefits of taking

Sisonke 'Confirm Identity' Screen (Details are Correct)

Sisonke Electronic Consent Portal

Confirm Identity

Please confirm that the details below are correct

First name(s)
Goitse mang

Surname
Nonyana

Cellular phone number
27*****847

[Details are incorrect](#) [Details are correct](#)

Upon successful verification of your identity by the EVDS, your name, surname and partial cellular phone number will be displayed.

- If your details are correct, please click **'Details are correct'**
- If your details are incorrect please click **'Details are incorrect and proceed back to the EVDS registration Portal'**

Sisonke 'Agreement to Participate': 6 x Yes/No Questions ('Yes' required)

Sisonke Electronic Consent Portal

Your Agreement to Participate

If you agree to join the study, please answer all the questions below. You will not be able to proceed and receive enrollment confirmation if you do not answer Yes.

Question 1
I have read and understood the Sisonke Participant Information Leaflet & Info document.

Click to select response

Yes

Question 2
All my questions about the study, the Ad26.COVID.2.S experimental vaccine, and possible risks and benefits have been answered to my satisfaction.

Click to select response

Yes

Question 3
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 Sponsors database and understand that any data shared and used for the

Your **Agreement to Participate** consists of **six** Yes/No questions.

A '**Yes**' response to each of these questions is required to proceed with the electronic consent.

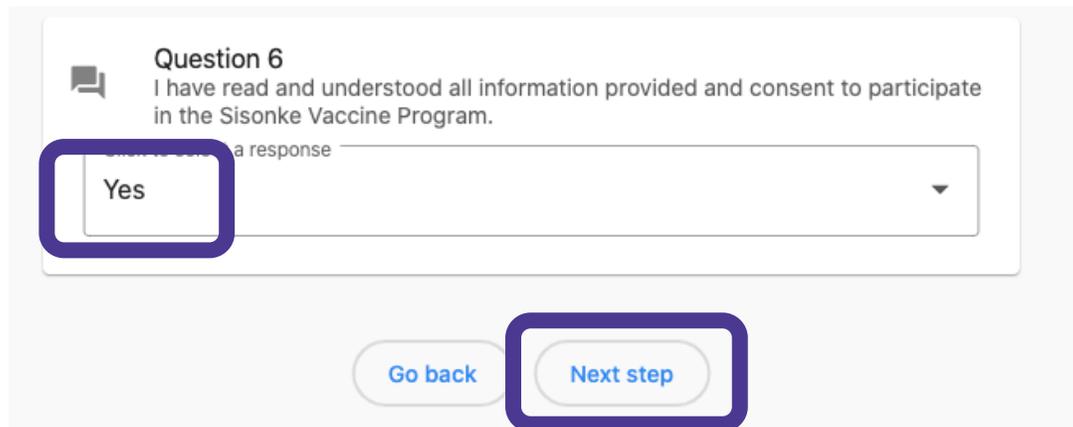
Sisonke eConsent 'No' response prompt ('Yes' required)

The screenshot shows the 'Sisonke Electronic Consent Portal' interface. At the top, there is a green header with the text 'Sisonke Electronic Consent Portal'. Below the header, there is a paragraph of text: '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)'. Below this text is a dropdown menu with the text 'Click to select a response' and the option 'No' selected. Below the dropdown menu, there is a red box containing the text: 'You will not be able to proceed and receive enrollment confirmation if you do not answer Y'. Below this, there are three questions, each with a dropdown menu. Question 4: '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.' The dropdown menu has 'Yes' selected. Question 5: 'If a caregiver is required, I consent to allow my designated caregiver to provide support with my study related activities.' The dropdown menu has 'Yes' selected. Question 6: 'I have read and understood all information provided and consent to participate in the Sisonke Vaccine Program.' The dropdown menu has 'Yes' selected. At the bottom of the form, there are two buttons: 'Go back' and 'Next step'.

Your **Agreement to Participate** consists of **six** Yes/No questions.

Any '**No**' response to any of these questions will receive a prompt:
"You will not be able to proceed and receive enrollment confirmation if you do not answer Yes"

Sisonke eConsent final enrolment question (6 of 6)



Question 6
I have read and understood all information provided and consent to participate in the Sisonke Vaccine Program.

a response

Yes

Go back Next step

Question 6 asks the consentee to confirm:

'I have read and understood all information provided and consent to participate in the Sisonke Vaccine Program'

A **'Yes'** response to all 6 questions will enable the consentee to successfully click **'Next Step'**

Accept Terms & Conditions

Sisonke Electronic Consent Portal

Terms and Conditions

I accept the terms and conditions below.

[Go back](#) [Submit](#)

↑ Terms and Conditions

J & J Consent Portal – DATA PROTECTION & PRIVACY POLICY

Privacy Policy

This is the Privacy Policy of the J&J Consent Portal (CP) In this document, “we”, “our”, or “us” refer to South African Medical Research Council (SAMRC).

1. Introduction

1.1. SAMRC has developed the CP to support the COVID-19 Vaccination research in South Africa.

1.2. The CP will be used to capture COVID-19 vaccination events digitally and provide data to the SAMRC data analytics platform to monitor and report on.

1.3. “Personal information” shall have the same meaning as in the Protection of Personal Information Act No. 4 of 2013.

1.4. “Processing” means any operation with personal data, irrespective of the means applied and the procedure, and in particular the collection, storage, use, revision, disclosure, archiving, or destruction of data.

1.5 The processing of personal data is managed in line with the provisions and safeguards set out in the Protection of Personal Information Act No. 4 of 2013.

2. Responsible Party

- Please accept the terms and conditions by **ticking the box** and clicking **Submit**
- The Terms and Conditions are available **on-screen**.

Sisonke eConsent successful submission confirmation

Sisonke Electronic Consent Portal

Submission has been successful.

- The final screen will confirm that your **enrolment has been successful**.
- You will receive an **SMS notification** confirming enrolment, including the **Vaccine Voucher Number** (SMS #3).

Dear [Name], you have successfully enrolled into the Sisonke Vaccine Program. We look forward to welcoming you at [Site Name]. Your voucher number is [Voucher Number]. This Voucher along with your ID document/passport is required at the Vaccination Site. For public sector HCWs, please contact the Vaccine Site directly. The vaccination roster for private HCWs is through the Hospital or GP organizations.

3

EVDS Capturing at the Vaccine Site (“EVDS On-Site”)

