Sisonke Open Label Study:
INFORMED CONSENT FOR PREGNANT OR BREASTFEEDING HEALTH CARE WORKERS

An Open-label, Single-arm Phase 3B study to Monitor the Effectiveness of the Single Dose Ad26.COV2.S COVID-19 Vaccine among Health Care Workers in South Africa

Study name: Sisonke [TOGETHER]

Study number: VAC31518COV3012

Study Sponsor: South African Medical Research Council (SAMRC)

Study Doctor (Investigator): Prof Glenda Gray

PREGNANCY

The American college of Obstetricians and Gynecologists' Immunization, Infectious Disease and public Health Preparedness Expert Work Group, the USA Center for Disease Control and the WHO have recommended the JNJ vaccines for use in pregnant and lactating women. They have concluded that pregnant women and lactating women in the USA can receive the AD 26.COV2.S vaccine. Replication incompetent or replication defective virus vaccines are not contra-indicated in pregnancy. The same type of vaccine has been authorized for use in Ebola and has been studied extensively for other illnesses.

Although there is an ongoing Phase 2 study that assesses the safety and reactogenicity of the Ad26.COV2.S administered IM as part of a 2 dose schedule (28 days apart) in pregnant women in their 2nd or 3rd trimester (NCT04765384), the FDA EUA allows for its use in pregnancy.

Pregnancy has been reported in 8 participants in Ensemble 1 (4 vaccines and 4 placebo). Vaccination was within 30 days of last menstrual period. Outcomes include spontaneous abortion (1 vaccine; 0 placebo); incomplete abortion (0 vaccine; 1 placebo); elective abortion (0 vaccine; 2 placebo) and ectopic pregnancy (1 vaccine; 0 placebo).

The Sisonke 3B study has been reviewed and approved by the SAHPRA and related Ethics Committees.

Pregnant women will be eligible to participate in the Sisonke Study after they have consulted with their treating obstetrician or doctor, and after evaluation by the research staff for any underlying illnesses or allergies.

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.

The Sisonke study will evaluate the number of participants with pregnancy outcomes (including live-births, live preterm birth, still born or abortion). We will also evaluate the number of participants with pregnancy related AEs. For neonates/infants born will be followed up passively through the safety desk.
If you are pregnant, you may be enrolled and vaccinated if

- You are between 16-34 weeks pregnant.
- You bring a letter of recommendation from your antenatal care provider to establish how many weeks pregnant you are and whether they support vaccination for you
- Sign an additional consent to vaccination at site

BREASTFEEDING

COVID-19 vaccines are not able to replicate in the human body, disintegrate within 2-3 days of vaccination, and do not pass into breastmilk. Breastfeeding women have been included in all trials of the JnJ vaccine thus far, with no safety concerns reported in mothers or their infants.
It is considered safe to breastfeed during this study.

If you have questions about this study, or you have any symptoms that you think may be related to this study, contact Sisonke Desk: 0800 014 956.

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 this committee. If you have questions about your rights as a research participant, or problems or concerns about how you are being treated in this study, contact South African Medical Research Council Ethics Committee at the below detail. The South African Medical Research Council Ethics Committee is an independent committee established to help protect the rights of research participants.

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

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, the Ethics in Health Research: Principles, Structures and Processes Second Edition 2015, and Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa. We can provide you with copies of these guidelines if you wish to review them.

In addition, the recent Protection of Personal Information Act (POPIA) ensures that all South African institutions conducts themselves in a responsible manner when collecting, processing, storing and sharing another entity's personal information by holding them accountable should they abuse or compromise your personal information in any way.

South African Health Products Regulatory Authority (SAHPRA)

If you have questions about this study, you should first discuss them with your doctor or the ethics committee (contact details as provided on this form). After you have consulted your doctor or the ethics committee and if they have not provided you with answers to your satisfaction, you should write to the South African Health Products Regulatory Authority (SAHPRA) at:

The Chief Executive Officer
Dr Buitumelo Semete-Makokotlela
South African Health Products Regulatory Authority
Department of Health
Private Bag X828
PRETORIA
0001
Tel: 012 501 0410/13
e-mail: Boitumelo.Semete@sahpra.org.za

YOUR AGREEMENT TO PARTICIPATE
If you agree to join the study, please read and then sign below.

- I have read and understood this information.
- I am pregnant and confirm I am >16 weeks and less than 34 weeks pregnant or I am breastfeeding.
- If pregnant, I have also consulted with my antenatal care provider and have am happy that vaccination is the right decision for me. I have brought a letter to confirm my dates.
- This informed consent registers that my questions have been answered.
- I also understand that the Sisonke Safety desk staff will collect information about your pregnancy and the health of my baby.
- 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.
- 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 ☐

Participant's name (print)	Participant's signature or mark	Date	Time

Clinic staff conducting consent discussion (print)	Clinic staff signature	Date	Time

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

Witness's name (print)	Witness's signature	Date	Time

*Witness is impartial and was present for the entire discussion of this consent form.