



OFFICE OF THE PRESIDENT
OF THE SOUTH AFRICAN MEDICAL
RESEARCH COUNCIL

8th February 2021

Attention:
Dr Boitemelo Semete
The Chief Executive Officer
South African Health Products Regulatory Authority (SAHPRA)
Clinical Trial Unit
Building A
Loftus Park
416 Kirkness Street
Arcadia
Pretoria
0083

Dear Dr Semete

RE: Application to conduct a the COV3001-Phase 3B Open Label Study

Title: 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

We are excited to submit our application to conduct a phase 3B open-label study to evaluate the Janssen Ad26 COVID-19 vaccine amongst health care workers in South Africa. This study is an extension of the phase 3 study (ref VAC31518COV3001), A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED PHASE 3 STUDY TO ASSESS THE EFFICACY ANDSAFETY OF AD26.COVS FOR THE PREVENTION OF SARS-COV-2-MEDIATED COVID-19 IN ADULTS AGED 18 YEARS AND OLDER SAHPRA Reference Number: 20200434).

This phase 3B study is aimed at health care workers in both the private and public sector. The Ensemble study sites will work closely with the National Vaccination Sites to ensure the execution of this study.

Please find attached our documentation.

- 1. Cover page**
- 2. Clinical Trial Application Form (CTF1) in both PDF and Word format**
- 3. Protocol Version 1.0, Dated 08 February 2021**
- 4. Participant Information Sheet and Informed Consent Form Version 1.0, Dated 08 February 2021**
- 5. Signed Declaration by Applicant**
- 6. Signed Declaration by National Principal Investigators**



7. **Proof of Application to Register the Trial on the South African National Clinical Trials Register**
8. **References**

Kind Regards



President/CEO

Prof Glenda E Gray MBBCH, FCPaedS (SA), DSc (honoris causa SFU), DSc (honoris causa SUN), LL.D (honoris causa Rhodes).

Member Paediatrics Faculty of Health Sciences, University of the Witwatersrand

Member African Academy of Sciences South Africa

Member of the Institute of Medicine of the National Academies, USA

Member American Society for Microbiology,