Project Brief: Jansen ENSEMBLE VAC31518COV3001 HG

Full Title of Study/Programme	A Randomized , Double -Blinded, Placebo-Controlled Phase 3 Study to assess the Efficacy and safety of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults Aged 18 Years and Older.
Technical Focus Area	Research (Adults)
Rationale	The development of a vaccine for Coronavirus disease -19 (COVID-19) will be critical for containing the current outbreak and preventing future outbreaks, as no vaccine is currently available. Janssen is developing a vaccine for the prevention of SARS-CoV-2-mediated COVID-19 in adults. In this study efficacy, safety and Immunogenicity will be evaluated in adults living in or going to locations with high risk of SARS-CoV-2 infection after vaccine administration.
Primary Objectives	To demonstrate the efficacy of AD26.COV2.S in the prevention of molecularly confirmed moderate to severe/critical COVID-19, as compared to Placebo, in SARS-CoV-2 Seronegative adults.
Secondary Objectives (1/2)	Prevention of molecularly confirmed, moderate to severe/critical COVID-19, as compared to Placebo. Efficacy of Ad26.COV2.S in the prevention of molecularly confirmed, moderate to severe/critical COVID-19 in SARS-CoV-2 Seronegative adults, as compared to Placebo, with onset 1 day after study vaccination. Effect of Ad26.CoV2.S requiring medical intervention(based on objective criteria) compared to Placebo. Effect of Ad26.COV2.S on SARS-CoV-2 viral RNA load compared to Placebo for moderate to severe/critical COVID-19
Secondary Objectives (2/2)	Effect of Ad26.COV2.S on • molecularly confirmed mild COVID-19 • COVID-19 as defined by US FDA harmonized case definition • all molecularly confirmed symptomatic COVID-19, as compared to placebo • occurrence of asymptomatic or undetected infections with SARS-CoV-2, as compared to placebo
Primary Endpoint/Outcome	First occurrence of molecularly confirmed moderate to severe/critical COVID-19, with onset at least 28 days post vaccination
Study Design (R)	This is a randomized, Double-Blind , Placebo-Controlled Phase 3 Study. Enrolment will be staggered in 2 stages.
Study arms (R)	Stage 1 1A Healthy ≥ 18 to <60 year old adults without relevant comorbidities

	1B ≥ 18 to < 60 year old adults with and without relevant comorbidities Stage 2. To enrol minimum of 25% of study population 2A Healthy ≥ 60 year old adults without relevant comorbidities 2B ≥ 60 year old adults with or without relevant comorbidities
Study population (R)	Adults 18 Years and Older
Study sample size (R)	Between 30,000 to 60,000 adult participants will be enrolled and randomized 1:1 to 1 of 2 groups.
Follow up/duration	Study Participants will be followed-up for 2 years and 1 Month.
Study/Programme sites	COVPN and IQVIA multinational sites
Study/Programme duration	The total duration of the study will be 24 months from the day of enrolment for all participants.
Investigators	Dr Faeezah Patel, Principal Investigator Dr Elizea Horne, Co-Principal Investigator Dr Lee Fairlie, Sub Investigator Dr Masebole Masenya, Sub Investigator Dr Gabrielle Benade, Sub Investigator Dr Alden Nicholas Geldenhuys, Sub Investigator
Other Partners & Collaborators	CoVPN, HVTN and IQVIA
Sponsors/Donors	Janssen Pharmaceutical Companies of Johnson Johnson
Publications/key presentations to date	Nil to date
Progress Update as at Oct 2020	Site Initiation stage
Frequency of donor narrative report	Annual
Overall Study/Project Contact	Dr Hermien Gous (hgous@wrhi.ac.za)
Briefing owner and date	Dr Hermien Gous 22 Oct 2020 Dr Faeezah Patel Dr Elizea Horne 22 Oct 2020