

Study of recombinant protein vaccines with adjuvant as a primary series and as a booster dose against COVID-19 in adults 18 years of age and older (VAT00002)

Study Design



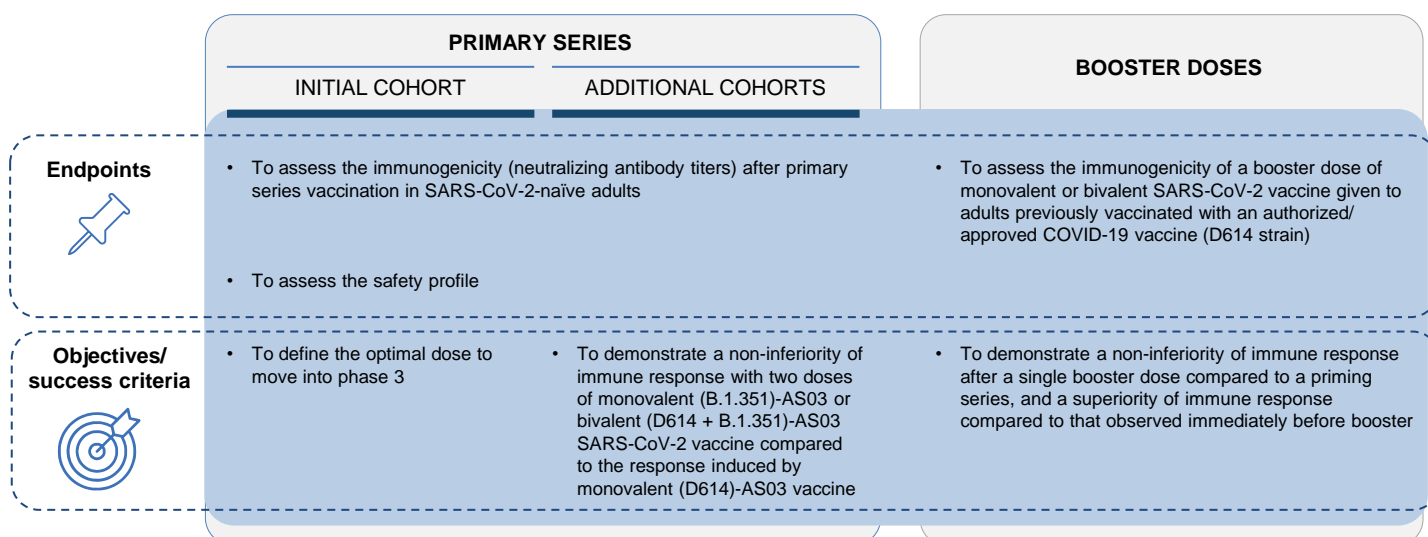
VACCINES FORMULATION

- CoV2 preS dTM (recombinant) with AS03 adjuvant
- Monovalent (D614) adjuvanted, Monovalent (B.1.351) with or without AS03 adjuvant and bivalent (D614 + B.1.351) adjuvanted formulations
- Intramuscular injection; vaccine storage between 2 – 8°C



STUDY TYPE

Phase 2/3 randomized multi-center study, double-blind and open label cohorts



DESIGN



>5000 participants including subjects who completed a COVID primo-vaccination schedule authorized/conditionally approved COVID-19 vaccine (booster dose cohorts) and the SARS-CoV-2 naïve participants (initial cohort and supplemental cohorts)

INITIAL COHORT



SARS-CoV2 naïve adults



3 different antigen doses:
5µg, 10µg, and 15µg

Monovalent (D614)-AS03



US and Honduras

ADDITIONAL COHORTS

BOOSTER DOSE COHORTS



Volunteers who previously completed the primary series



Single booster dose

Monovalent (D614)-AS03
Or
Bivalent (D614 + B.1.351)-AS03
Or
Monovalent (B.1.351) with or without AS03 adjuvant

SUPPLEMENTAL PRIMARY SERIES



SARS-CoV2 naïve adults – 18-55 years old



2 doses

Monovalent (D614)-AS03
Or
Monovalent (B.1.351)-AS03
Or
Bivalent (D614 + B.1.351)-AS03

INCLUSION CRITERIA



- 18 years old or older
- Able to attend all trial visits and comply with all study procedures
- **BOOSTER DOSE COHORTS:** Participants who received a complete primary vaccination series with an authorized/ conditionally approved COVID-19 vaccine (mRNA or adenovirus-vectored) or participants from VAT00002 initial cohort (primed with the protein subunit candidate vaccine), with the last dose administered between 4 to 10 months prior to inclusion

EXCLUSION CRITERIA



- Individuals who received any vaccine in the within 30 days preceding the first study vaccination, or following the second injection (except influenza vaccine)
- Pregnant or breastfeeding women

