

# A Safety and Immunogenicity Trial of Boost-2867 Vaccine, Via Intranasal and Intramuscular Routes

NCT07221162

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Status	RECRUITING
Phase	Phase 1
Sponsor	National Institute of Allergy and Infectious Diseases (NIAID)
Enrollment	140 participants

## Key Eligibility Criteria

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### Inclusion (15)

- Provides written informed consent before initiation of any study procedures.
- Able to understand and agree to comply with planned study procedures and be available for all study visits.
- Non-pregnant adults, 18 through 64 years of age at the time of study product administration.
- Participants of childbearing potential\* must agree to use or have practiced true abstinence\*\* or use at least one acceptable primary form of contraception\*\*\*.
- These criteria apply to females who are in a heterosexual relationship who are of childbearing potential. Not of childbearing potential include post-menopausal females (defined as having a history of amenorrhea for at least one year) or a documented status as being surgically sterile (hysterectomy, bilateral oophorectomy, or tubal ligation/salpingectomy).

... and 10 more (see full listing online)

### Exclusion (31)

- Positive SARS-CoV-2 PCR at screening.
- Abnormal vital signs (Grade 1 or higher):
  - \*Grade 1 or higher is equivalent to: Systolic blood pressure (SBP)  $\geq$  141 mmHg or  $\leq$  89 mmHg Diastolic blood pressure (DBP)  $\geq$  91 mmHg Heart rate (HR) is  $\geq$  101 beats per minute or  $\leq$  54 beats per minute Oral temperature  $\geq$  38.0 degrees Celsius (100.4 degrees Fahrenheit)
- Self-reported or medically documented SARS-CoV-2 infection (regardless of whether symptomatic or asymptomatic) within 16 weeks prior to study product administration.
- Participant who is pregnant or breastfeeding.

... and 26 more (see full listing online)

## Locations (8 total)

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University of California San Francisco - Zuckerberg San Francisco General Hospital - Division of Human Immunodeficiency Virus, Infectious Disease, and Global Medicine, San Francisco, California, United States

Center for Immunization Research, Johns Hopkins Bloomberg School Public Health, Baltimore, Maryland, United States

Saint Louis University Center for Vaccine Development, St Louis, Missouri, United States

... and 5 more locations