CARE ID
Clinical Alliance for Research & Education Infectious Diseases, LLC
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Pfizer COVID-19 Vaccine Study

August 2020

GENERAL ELIGIBILITY CRITERIA

INCLUSION CRITERIA

Participants are eligible to be included in this study only if all of the following criteria apply:

1. **Age and Sex**:
   Male or female participants between the age of 18 and 85 at the time of enrollment
2. Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures. *(See Consent document)*
3. Healthy participants who are determined by medical history, physical examination and clinical judgment of the investigator to be eligible for inclusion in the study.

   Note: Healthy participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, can be included.
4. Participants who, in the judgment of the investigator, are at risk for acquiring COVID-19.
5. Capable of giving personal signed informed consent

EXCLUSION CRITERIA

Participants are excluded from the study if any of the following criteria apply:

Medical Conditions:

1. Other medical or psychiatric condition including recent (within the past year) or active suicidal ideation/behavior or laboratory abnormality that may increase the risk of study participation or, in the investigator's judgment, make the participant inappropriate for the study.
2. Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV).
3. History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (e.g., anaphylaxis) to any component of the study intervention(s).
4. Receipt of medications intended to prevent COVID-19.
5. Previous clinical or microbiological diagnosis of COVID-19.
6. Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination.

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EXCLUSION CRITERIA (*continued)*

Potential Exclusions:

7. Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention.
8. Current use of blood thinners, in the opinion of the investigator, contraindicate intramuscular injection.
9. Women who are pregnant or breastfeeding.

Prior/Concomitant Therapy:

10. Previous vaccination with any coronavirus vaccine.
11. Individuals who receive treatment with immunosuppressive therapy, such as chemotherapy oral corticosteroids (such as Prednisone); short-term use of corticosteroids (< 14 days) for an acute illness are allowed but last dose should be at least 28 days prior to receiving the study vaccination
12. Receipt of blood/plasma products or immunoglobulin, from 60 days before study
13. Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation.
14. Previous participation in other studies involving study intervention containing lipid nanoparticles.

GUIDELINES FOR OTHER VACCINATIONS DURING THIS CLINICAL TRIAL:

1. Influenza vaccine should be received either 14 days before study injection #1 or 14 days after study injection #2
2. Pneumonia or shingles vaccine should be received either 28 days before study injection #1 or 28 days after injection #2