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CoVPN 3001 A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine SDMC

Project Number	Former Number	Contact PI/Project Leader	Awardee Organization
3UM1AI068635-14S2	3UM1AI068635-14S1	GILBERT, PETER B.	FRED HUTCHINSON CANCER RESEARCH CENTER

Description

Abstract Text

Project Abstract This proposal outlines the scientific agenda for the **COVID**-19 Prevention Network (CoVPN) Vaccines Leadership Operations Center (LOC) for implementation of the first **COVID**-19 **vaccine** efficacy trial “A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 **Vaccine** in Adults Aged 18 Years and Older.” With the global **COVID**-19 pandemic, we recognize a significant need for vaccines that modify **COVID**-19 in SARS-CoV-2 infected individuals. Addressing this gap, the HVTN has joined 4 other National Institute of Health (NIH) clinical trial networks to form the CoVPN, an enhanced network dedicated to developing globally effective vaccines for SARS-CoV-2. Due to its extensive experience implementing HIV **vaccine** trials, the HIV **Vaccine** Trials Network (HVTN) LOC was selected to as the CoVPN **vaccine** LOC. This trial, a phase 3, placebo-controlled, double-blinded study will test the efficacy of mRNA-1273 SARS-CoV- 2, a lipid co-formulated messenger ribonucleic acid (mRNA) **vaccine** encoding the SARS-CoV-2 spike protein (S), to modify **COVID**-19 disease in adults 18 year of age and older. Participants will be recruited from clinical trial sites across the US, using data analytics to target high risk individuals with a diverse racial and ethnic profile. In addition, the CoVPN will use accessory community-based sites, staffed by clinical teams from the home sites and employ mobile clinics to enroll individuals in new high risk settings (e.g., meat packing plants). Participants will receive symptomatic screening for SARS-CoV-2 infection, and if they become infected will be monitored with frequent clinical check-ins and remote monitoring of vital signs. Infected individuals who progress to moderate-severe **COVID**-19 will be referred for hospitalization. All trial endpoint assays will be done at CoVPN laboratories, using validated assays for diagnosis and immune monitoring. Specific aims of this study are to demonstrate efficacy of mRNA-1273 SARS-CoV-2 to prevent **COVID**-19, to evaluate the safety and reactogenicity of 2 injections given 28 days apart, the assess the ability to prevent infection with SARS-CoV-2, the assess the ability to modify **COVID**-19 infection, to evaluate viral infection kinetics, and to evaluate the **vaccine** induced immune response. This initial efficacy trial will tell us much about the adaptive immune response in persons who receive a SARS-CoV-2 S protein based **vaccine** and about their ability to modify the disease course of **COVID**-19. In addition, it will improve our understanding of the dynamics and duration of these responses and will inform rational design and testing of preventive and therapeutic monoclonal antibody interventions. Lastly, the results of this trial will be used to assess registration of this **vaccine** product as well as to modify future **COVID**-19 **vaccine** trials planned over the next 12 months.

Public Health Relevance Statement

Thank you for your feedback!

Project Narrative The outbreak of SARS-CoV-2 across the globe presents an unprecedented health risk to the world's population and requires intensive study of key gaps in our understanding of the immune response and what adaptations lead to protective immunity. In this study, the CoVPN will apply its world class laboratory, biostatistical and vaccine trial leadership expertise to assess this response in 30,000 persons at over 80 clinical trial sites across the US. The goal of this protocol is to rapidly assess the efficacy of mRNA-1273 to modify the severity of COVID-19 disease in SARS-CoV-2 infected individuals.

NIH Spending Category

Biotechnology **Clinical Research** **Clinical Trials and Supportive Activities** **Coronaviruses** **Emerging Infectious Diseases** **Immunization** **Infectious Diseases** **Prevention** **Vaccine Related**

Project Terms

18 year old **2019-nCoV** **Address** **Adult** **Age-Years** **Biological Assay** **Biometry** **COVID-19** **COVID-19 pandemic** **COVID-19 vaccine** **Cause of Death** **Cellular Assay** **Clinic** **Clinical** **Clinical Trials** **Clinical Trials Network** **Cohort Studies** **Communicable Diseases** **Communities** **Data Analytics** **Development** **Diagnosis** **Disease** **Disease Outbreaks** **Double-Blind Method** **End Point Assay** **Enrollment** **Exposure to** **Eye** **Future** **Goals** **HIV Vaccine Trials Network** **HIV vaccine** **Health** **Home environment** **Hospitalization** **Immune** **Immune response** **Immunity**

Read More

Details

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Unavailable

Organization Type
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Congressional District
07

Other Information

FOA
PA-18-591

Study Section

Administering Institutes or Centers
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Project Start Date **20-August-2020**

Project End **06-July-**

Thank you for your feedback!

DUNS Number **078200995**
CFDA Code **855**
Budget Start Date **20-August-2020**
Budget End Date **06-July-2021**
Award Notice Date **20-August-2020**
Fiscal Year **2020**

Project Funding Information for 2020

Total Funding **$1,414,274**
Direct Costs **$833,095**
Indirect Costs **$581,179**

Year	Funding IC	
2020	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	$1,414,274

NIH Categorical Spending

Click here for more information on NIH Categorical Spending

Funding IC	FY Total Cost by IC	NIH Spending Category
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	$316,670	Biotechnology; Clinical Research; Clinical Trials and Supportive Activities; Coronaviruses; Emerging Infectious Diseases; Immunization; Infectious Diseases; Prevention; Vaccine Related;

Sub Projects

No Sub Projects information available for 3UM1AI068635-14S2

Publications

No Publications available for 3UM1AI068635-14S2

Patents

No Patents information available for 3UM1AI068635-14S2

Outcomes

The Project Outcomes shown here are displayed verbatim as submitted by the Principal Investigator (PI) for this award. Any opinions, findings, and conclusions or recommendations expressed are those of the PI and do not necessarily reflect the views of the National Institutes of Health. NIH has not endorsed the content below.

No Outcomes available for 3UM1AI068635-14S2

Thank you for your feedback!

Clinical Studies

No Clinical Studies information available for 3UM1AI068635-14S2

News and More

Related News Releases

No news release information available for 3UM1AI068635-14S2

History

No Historical information available for 3UM1AI068635-14S2

Similar Projects

No Similar Projects information available for 3UM1AI068635-14S2

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