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COVID-19 Serosurveys and Vaccine Study Site Preparations

Project Number
1ZIAAI001261-01

Contact PI/Project Leader
DUFFY, PATRICK

Awardee Organization
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Description

Abstract Text

LMIV produced and obtained antigens for multiple **COVID**-19 serology assays. First, plasmids were obtained for production of full-length spike and RBD used in the assay developed by Florian Krammer at Mount Sinai Hospital in New York. After 3 successful production runs of **COVID**-19 spike proteins used in the Krammer assay, the in-house proteins were shown to perform in a manner identical to proteins produced in the Krammer group. Second, proteins were produced and obtained for a serological assay developed by Kaitlyn Sadtler (NIBIB). LMIV initiated a collaboration with Dominic Esposito (NCI) and obtained enough protein for the entire serological survey program in Africa. LMIV also obtained the plasmids for both proteins used in the Sadtler assay and produced at high yields the RBD protein to be used for in house assay development. Third, LMIV designed a construct expressing the full-length nucleocapsid protein in mammalian cells and produced full-length nucleocapsid at high levels to use in serology assay to compare to spike and RBD. Fourth, LMIV constructed a plasmid and expressed the Ace2 binding domain and demonstrated binding of RBD to Ace2 in an ELISA based format establishing an assay at LMIV that can be used to evaluate antibodies that block Ace2 binding to RBD and spike. Additionally, the first **COVID**-19 animal immunization was performed at LMIV and this study demonstrated immunogenicity of spike and RBD in mice instituting a benchmark for LMIV going forward for new immunogen design. SARS-CoV-2 antigens (full-length Spike (S) and Receptor binding domain (RBD)) from commercial sources (Ray Biotech, US) and academic partner laboratories (**Vaccine** Research Center, NIH; Icahn School of Medicine at Mt Sinai; Ragon institute, MGH, MIT)) were compared using either the assay established by the Krammer laboratory (Mt Sinai) or the Sadtler laboratory (NIBIB, NIH), as per their defined standard operating procedures. In addition, antibodies against the Nucleocapsid (N) protein (antigen produced at LMIV) were measured using the Sadtler assay. US **COVID** nave (n =20), acute convalescent sera samples from US COVID19 patients (n=114) and Mali sera from three active cohorts (Bancoumana, Ouelessebougou and Kalifabougou, n = 248) were screened (in duplicates) for reactivity to **COVID**-19 antigens. In addition, the Malian sera were also screened for antibodies against Spike proteins from other known betacoronaviruses (SARS, MERS, OC43 and HKU1) kindly provided by Kaitlyn Sadtler. In July 2020, we commenced a community **COVID**-19 seroprevalence study at existing clinical trials sites in Mali. This study is a Public Health Surveillance Activity in collaboration with the Ministry of Health in Mali to describe the sero-epidemiology of **COVID**-19 in urban and rural populations. Using the demographic and clinical information collected from participants, we will describe the age-stratified seroprevalence and fraction of asymptomatic/pauci-symptomatic cases to help understand the penetration of SARS-CoV-2 into the community. In parallel to the serosurvey program described above, LMIV has initiated a project on developing **vaccine** candidates against SARS-CoV-2 to address the pandemic caused by this virus. As part of this parallel program, we used antigens generated in the Serosurvey program as benchmark immunogens to pilot small animal immunization studies and platforms. LMIV has over the years developed a Conjugate Nanoparticle **Vaccine** technology for malaria using a synthetic approach that generates a nanoparticle structure with antigen and a carrier protein are crosslinked at an approximately 1:1 ratio. A malaria transmission blocking **vaccine** employing this technology is currently undergoing Phase II clinical trial in malaria endemic areas in Mali. This technology has proven effective in enhancing the immunogenicity of poorly immunogenic subunit protein antigens. We have adapted this technology to develop a second-generation **vaccine** against SARS-CoV-2 using the Receptor Binding Domain (RBD) of the Spike protein as the antigen. RDB is not a highly immunogenic protein, but conjugating this to a carrier protein, we believe, will make the conjugate an effective **vaccine** candidate. By using RBD as antigen, we hope to focus the immune response to the receptor binding interface and generate potent neutralizing monoclonal antibody that blocks the virus binding to ACE2 receptor. Thus far we have synthesized and characterized a number of chemically crosslinked conjugates of two different RBD constructs to a carrier protein EcoCRM. This carrier is shown to be an effective

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Data not available.

NIH Spending Category

Bioengineering Biotechnology Clinical Research Clinical Trials and Supportive Activities Coronaviruses Emerging Infectious Diseases Immunization Infectious Diseases Lung Malaria Malaria Vaccine Nanotechnology Orphan Drug Prevention Rare Diseases Rural Health Vaccine Related Vector-Borne Diseases

Project Terms

2019-nCoV Acute Address Adjuvant Africa Age Animals Antibodies Antigens Area Benchmarking Binding Biological Assay Biotechnology Blocking Antibodies COVID-19 COVID-19 pandemic COVID-19 vaccine Carrier Proteins Chemicals Clinical Clinical Trials Collaborations Communities Enzyme-Linked Immunosorbent Assay Epidemiology Generations Goals Health Hospitals Household Immune response Immunization Individual Institutes Laboratories Length Malaria Malaria Vaccines Mali Mammalian Cell Measures Middle East Respiratory Syndrome Mus

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No information available for 1ZIAAI001261-01

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Publications

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