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Similar Projects

Project 2: Current Good Manufacture Practices (CGMP) Production of Nucleoside-Modified mRNAs Encoding HIV-1 Envelopes

Parent Project Number	Sub-Project ID	Contact PI/Project Leader	Awardee Organization
5U19AI135902-03	5334	PORTER, FREDERICK	DUKE UNIVERSITY

Description

Abstract Text

Project 2: Current Good Manufacture Practices (CGMP) Production of Nucleoside-Modified mRNAs Encoding HIV-1 Envelopes This IPCAVD grant seeks to develop and evaluate **mRNA** as an HIV-1 **vaccine** platform. Project 2 will oversee the manufacture of two nucleoside-modified mRNAs by current good manufacturing practices (CGMP) for a Phase I clinical trial to begin in year 5. To execute this project, we will select contract development and manufacturing organizations (CDMOs) as commercial partners to manufacture two **mRNA** immunogens to induce V3-glycan envelope site-targeted bnAb precursors. The scope of this work will span knowledge transfer to the selected CDMO through successful IND filing for the final **vaccine** candidate. A technical CDMO management team, including Drs. Haynes, Weissman and Porter will be assembled to oversee the process and ensure successful delivery of the program. The following specific aims are proposed for the project. • Aim 1. Facilitate knowledge transfer for selected **mRNA** immunogens to CDMOs. • Aim 2. Deliver final drug substances and drug products for toxicology studies and clinical testing. • Aim 3. Develop and deliver regulatory strategy to enable Phase I proof of concept clinical studies. Project 2 will advance modified **mRNA** as a platform for HIV immunization and establish the regulatory framework for its use. CGMP production of an **mRNA** V3-glycan mimetope **vaccine** will allow this **vaccine** platform to be evaluated in humans for comparison to other vaccination strategies and to assess the induction of V3-glycan bnAb precursors. Once developed, this platform could be rapidly applied to other HIV-1 immunogens with little additional development since the production process and the majority of release methods are not sequence dependent. These features of modified **mRNA** position the platform to address the complexity, safety, and cost effectiveness of HIV-1 **vaccine** regimens.

Public Health Relevance Statement

Data not available.

NIH Spending Category

Biotechnology Genetics HIV/AIDS Immunization Infectious Diseases Prevention Vaccine Related Vaccine Related (AIDS)

Project Terms

Address Animal Model Animals Antibodies Antibody Response Antigens B-Lymphocytes Categories Cell Lineage Characteristics Chemicals Clinic Clinical Research Clinical Trials Complex Consumption Contracts Custom Development Dose Ensure Formulation Glycopeptides Goals Grant HIV HIV immunization HIV **vaccine** HIV-1 HIV-1 **vaccine** Human Immunity Knowledge Messenger RNA Methods Modification Mosaicism Nucleic Acids Nucleosides Pharmaceutical Preparations Phase Phase I Clinical Trials

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5U19AI135902-03	5334	PORTER, FREDERICK	DUKE UNIVERSITY

PORTER, FREDERICK

Email not available Email not available

Title

Contact
frederick.porter@duke.edu

Organization

Name	Department Type	State Code
DUKE UNIVERSITY	Unavailable	NC
City	**Organization Type**	**Congressional District**
DURHAM	Domestic Higher Education	04
Country		
UNITED STATES (US)		

Other Information

FOA	Administering Institutes or Centers	Project Start Date	
PAR-15-330	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	Project End Date	
Study Section		Budget Start Date	01-February-2020
ZAI1-JRR-A		Budget End Date	31-January-2021
Fiscal Year 2020	Award Notice Date 04-February-2020		
	DUNS Number 044387793 CFDA Code		

Project Funding Information for 2020

Total Funding	Direct Costs	Indirect Costs
$257,560	$159,975	$97,585

Year	Funding IC	
2020	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	$257,560

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	$87,961	Biotechnology; Genetics; HIV/AIDS; Immunization; Infectious Diseases; Prevention; Vaccine Related; Vaccine Related (AIDS);

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Related;
Vaccine
Related (AIDS);

Sub Projects

No Sub Projects information available for 5U19AI135902-03 5334

Publications

No Publications available for 5U19AI135902-03 5334

Patents

No Patents information available for 5U19AI135902-03 5334

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 5U19AI135902-03 5334

Clinical Studies

No Clinical Studies information available for 5U19AI135902-03 5334

News and More

Related News Releases

No news release information available for 5U19AI135902-03 5334

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