Share

Back to Search Results

Establishment and operation of a Vaccine Pilot Plant

Project Number
1ZIBAI005063-16

Contact PI/Project Leader
ARNOLD, FRANK

Awardee Organization
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Description

Abstract Text

The Vaccine Pilot Plant (VPP) a.k.a. Vaccine Clinical Materials Program (VCMP) is a multiuse facility designed to manufacture vaccines and therapeutic products for human clinical trials according to current Good Manufacturing Practices (cGMPs) required by the US Food and Drug Administration (FDA). The facility is composed of a warehouse to receive the raw materials, central process support facility to manufacture buffers and media components, manufacturing suites to produce active vaccine and therapeutic products, a filling suite to fill the product into vials for delivery to the clinic, Quality Control laboratories to test the vaccine product, and supporting office and utility space for staff and equipment. These areas all work in concert to take raw materials and turn them into vaccine product that can be evaluated in humans. Development of the facility was completed in 2005 and clinical manufacturing started in January 2006. Clinical trial materials for candidate HIV, Ebola, Marburg, Chikunguya, H5N1/ **pandemic** Influenza vaccines, universal influenza vaccines, Respiratory syncytial virus vaccines and Zika have been prepared.

Public Health Relevance Statement

Data not available.

NIH Spending Category

Biodefense Emerging Infectious Diseases HIV/AIDS Immunization Infectious Diseases Influenza Orphan Drug Pneumonia & Influenza Prevention Rare Diseases Vaccine Related Vaccine Related (AIDS)

Project Terms

Area Buffers Clinic Clinical Clinical Trials Contracts Development Ebola virus Equipment Facility Designs Frankfurt-Marburg Syndrome Virus HIV Human Influenza A Virus, H5N1 Subtype Laboratories National Institute of Allergy and Infectious Disease Phase Placebos Plants Process Production Quality Control Respiratory Syncytial Virus Vaccines Techniques Testing Therapeutic United States Food and Drug Administration Vaccine Production Vaccines Vial device Work Zika Virus clinical material influenza virus vaccine manufacturing process operation **pandemic** influenza preclinical safety programs safety study universal influenza vaccine vaccine evaluation

Details

Contact PI/ Project Leader

Name
ARNOLD, FRANK

Title

Contact
Email not available

Other PIs

Not Applicable

Program Official

Name

Contact
Email not available

Thank you for your feedback!

Organization

Name
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

City

Country

Department Type
Unavailable

Organization Type
Unavailable

State Code

Congressional District

Other Information

FOA

Study Section

Fiscal Year
2019

Award Notice Date

Administering Institutes or Centers
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

DUNS Number

CFDA Code

Project Start Date

Project End Date

Budget Start Date

Budget End Date

Project Funding Information for 2019

Total Funding
$32,433,046

Direct Costs
$0

Indirect Costs
$0

Year	Funding IC	FY Total Cost by IC
2019	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	$32,433,046

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	$3,356,946	Biodefense
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	$26,079,120	Vaccine Related (AIDS)
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	$27,451,705	HIV/AIDS
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	$32,433,046	Emerging Infectious Diseases; Immunization; Infectious Diseases; Influenza; Orphan Drug; Pneumonia & Influenza; Prevention; Rare Diseases; Vaccine Related;

Sub Projects

No Sub Projects information available for 1ZIBAI005063-16

Publications

Export

Journal (Link to PubMed abstract)	Authors	Publication Year	Similar Publications	CitedBy	iCite R
Safety, tolerability, and immunogenicity of the respiratory syncytial virus prefusion F subunit vaccine DS-Cav1: a phase 1, randomised, open-label, dose-escalation clinical trial.					
The Lancet. Respiratory medicine 2021 Oct; 9 (10) 1111-1120	Ruckwardt, Tracy J; Morabito, Kaitlyn M; Phung, Emily; Crank,	2021			
Effect of a Chikungunya Virus-Like Particle Vaccine on Safety and Tolerability Outcomes: A Randomized Clinical Trial.					
JAMA 2020 04 14; 323 (14) 1369-1377	Chen, Grace L; Coates, Emily E; Plummer, Sarah H; Carter,	2020			iCite 5.59
Delivery of human immunodeficiency virus vaccine vectors to the intestine induces enhanced mucosal cellular immunity.					
Journal of virology 2009 Jul; 83 (14) 7166-75	Wang, Lingshu; Cheng, Cheng; Ko, Sung-Youl; Kong, Wing-Pui;	2009			iCite 0.50

View All

View All

View All

Thank you for your feedback!

Patents

No Patents information available for 1ZIBAI005063-16

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 1ZIBAI005063-16

Clinical Studies

No Clinical Studies information available for 1ZIBAI005063-16

News and More

Related News Releases

No news release information available for 1ZIBAI005063-16

History

No Historical information available for 1ZIBAI005063-16

Similar Projects

No Similar Projects information available for 1ZIBAI005063-16

Thank you for your feedback!