In Vivo Efficacy Testing Core

Parent Project Number	Sub-Project ID	Contact PI/Project Leader	Awardee Organization
5U19AI142777-02	8147	CHANDRAN, KARTIK	ALBERT EINSTEIN COLLEGE OF MEDICINE

Description

Abstract Text

Abstract: Core C In vivo efficacy testing is an essential part of medical countermeasure (MCM) development. For hemorrhagic fever viruses (HFV), where human clinical trials are difficult or unethical to conduct, the Food and Drug Administration (FDA) instituted the animal rule. Licensure via the FDA animal rule requires efficacy testing in at least two surrogate animal models of human disease. In support of overall Prometheus objectives, Core C will execute in vivo efficacy testing of antibody-based MCMs derived from Projects I, II, and III in rodent and nonhuman primate (NHP) models of filovirus, hantavirus, and nairovirus disease. Rodent models of ebolavirus, hantavirus, and nairovirus disease will serve as the first in vivo screening mechanism to down-select monoclonal antibody (mAb)-based MCMs for further assessment in higher animal models. Hamster models of hantavirus infection and mouse models of **CCHFV** infection will be utilized to evaluate newly discovered mAbs from Project I and down-select lead mAbs for NHP testing. Core C will evaluate in vivo efficacy of mAbs with altered Fc effector functions from Project II in rodent models of disease to identify mAb modifications with optimal in vivo potency. The prophylactic efficacy of Project III DMAbs expressing ebolavirus, hantavirus, and **CCHFV**-specific mAbs will be evaluated first in rodent models of disease and lead DMAbs will be tested in NHPs. In vivo efficacy results from all Core C efforts will be funneled into Projects I, II, and III and Cores A and B for identification of lead mAb cocktails and/or DMAb constructs for advanced development discussions.

Public Health Relevance Statement

Project Narrative: Core C Ebolaviruses, hantaviruses, and nairoviruses cause fatal hemorrhagic fever in humans and there are currently no approved medical countermeasures (MCM) for any of these viruses. Due to high lethality and sporadic nature of hemorrhagic fever virus outbreaks, human clinical trials are unethical and impractical to conduct. Consequently, novel MCM development requires the use of surrogate animal models. Core C will support the Prometheus consortium by completing prophylactic and therapeutic efficacy testing of novel MCM developed by Projects I, II, and III in rodent and nonhuman primate models of disease.

NIH Spending Category

Biodefense Biotechnology Emerging Infectious Diseases Immunization Immunotherapy Infectious Diseases Orphan Drug Rare Diseases

Project Terms

Advanced Development Advisory Committees Animal Model Antibodies Antibody Therapy Back Benchmarking Bispecific Antibodies Bispecific Monoclonal Antibodies Categories Cavia Clinical Trials DNA Development Disease Disease Outbreaks Disease model Dose Ebola virus Engineering Filovirus Half-Life Hamsters Hantavirus Hantavirus Infections Human Individual Infection Institutes Lead Licensure Life Extension Longevity Macaca fascicularis Macaca mulatta Modeling Modification Monoclonal Antibodies Mus Mutation Nairovirus National Institute of Allergy and Infectious Disease Nature Recombinants Rodent Rodent Model Serum Testing Treatment Efficacy

Read More

Details

Contact PI/ Project Leader

Other PIs

Program Official

Thank you for your feedback!

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Organization

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Department Type
Unavailable

Organization Type
Domestic Higher Education

State Code
NY

Congressional District
14

Other Information

FOA
RFA-AI-17-042

Study Section
ZAI1-LG-M

Fiscal Year
2020

Award Notice Date
24-January-2020

Administering Institutes or Centers
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

DUNS Number
081266487

CFDA Code

Project Start Date

Project End Date

Budget Start Date
01-February-2020

Budget End Date
31-January-2021

Project Funding Information for 2020

Total Funding
$396,522

Direct Costs
$396,522

Indirect Costs
$0

Year	Funding IC	FY Total Cost by IC
2020	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	$396,522

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	$396,522	Biodefense; Biotechnology; Emerging Infectious Diseases; Immunization; Immunotherapy; Infectious Diseases; Orphan Drug; Rare Diseases;

Sub Projects

No Sub Projects information available for 5U19AI142777-02 8147

Publications

No Publications available for 5U19AI142777-02 8147

Patents

No Patents information available for 5U19AI142777-02 8147

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.

Thank you for your feedback!

No Outcomes available for 5U19AI142777-02 8147

Clinical Studies

No Clinical Studies information available for 5U19AI142777-02 8147

News and More

Related News Releases

No news release information available for 5U19AI142777-02 8147

History

No Historical information available for 5U19AI142777-02 8147

Similar Projects

No Similar Projects information available for 5U19AI142777-02 8147

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