Office of Biodefense, Research Resources, and Translational Research (OBRRTR)

Medical, Biomedical & Biodefense: Support to the Warfighter Symposium
June 12th, 2019
NIAID Emerging Infectious Diseases/Pathogens

NIAID's pathogen priority list is periodically reviewed and is subject to revision. The list, including the U.S. Department of Homeland Security, which determines threats to national security, and the Centers for Disease Control and Prevention, which is responsible for responding to emerging public health threats, is updated according to the latest scientific evidence. Category A pathogens are those organisms/biological agents that pose the greatest threat to national security because they:
- Can be easily disseminated or transmitted from person to person
- Result in high mortality rates and have the potential for major public health impact
- Might cause public panic and social disruption
- Require special action for public health preparedness

Category B pathogens are the second highest priority organisms/biological agents and are moderately easy to disseminate, are associated with moderate morbidity rates and low mortality rates, and exist in the environment or are in the course of being domesticated. Examples include tick-borne and vector-borne pathogens, such as tularemia, anthrax, and Lyme disease.

The Journal of Infectious Diseases

NIH A Universal Influenza Vaccine: The Strategic Plan for the National Institute of Allergy and Infectious Diseases

National Institute of Allergy and Infectious Diseases
OBRRTR’s Mission

1. ‘PHEMCE’: Address USG’s identified biodefense and public health needs
   • Execute and represent NIH’s BioD and public health emergency R&D to the PHEMCE

2. Product Development: advance candidate MCMs and Platform Technologies (via BAAs/Contracts)
   - Biothreats = PHEMCE requirements based on DHS assessments
   - EID’s and other public health threats
   - Regulatory path - Animal rule, accelerated approval, or EUA
   - Transition to BARDA or industry

3. Translational Research: facilitate and manage…..
   - Pre-Clinical Services
   - Partnerships Program (grants)
   - CETRs (grants)
   - Containment Facilities/Infrastructure
   • Concept Acceleration Program (CAP)
OBRRTR’s Strategy & Approach

Preclinical Services
Modular Gap-Filling Studies

Promising candidates & technologies - non-funded external requestors

Promising candidates & technologies - NIH Funded Grants, SBIRs

Product Dev Contracts
MCM Candidates & Technologies to Ph I/II

Integrated
• Move MCMs along critical path
• Go-no-go decisions
• De-risk platforms & technologies
• Outbreak response

Gap filling studies for PD efforts

Adv. promising candidates & tech

Outbreak response:
Leverage PCS

Promising candidates & technologies - NIH Funded Grants, SBIRs

Support of early clinical trials is a critical milestone for transition to advanced development funding (e.g., BARDA)

17 products have transitioned to adv. dev., 8 have been FDA approved
Suite of service contracts that provide a broad range of assays and capabilities to the extramural community free-of-charge

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<th>Therapeutics</th>
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<td><em>In Vitro</em> Antimicrobial Activity</td>
<td>Testing</td>
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<td>Synthesis, ADME &amp; Tox Profiling</td>
<td>Manufacturing</td>
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### Animal Models

**DMID Preclinical Services**

**Research Resources**

**National Institute of Allergy and Infectious Diseases**

**NIH**

**SUPPORTING INFECTIOUS DISEASE RESEARCH**

**b ei RESOURCES**
DMID Clinical Services to Support Product Development

Product Development Pathway

Basic Research
Hypothesis Development and Testing

Discovery

Preclinical Development
IDE- and IND-Enabling Activities

Research Tools and Biological Materials

Clinical Evaluation

Diagnostics Vaccines Therapeutics

- Phase 1 Clinical Trial Units for Therapeutics
- Vaccine & Treatment Evaluation Units (VTEU’s, Ph I-IV)
- Clinical sample access, e.g., for diagnostics validation
# Snapshot: PCS Vaccine Testing During Recent Outbreaks

## Influenza
- Rapidly tested >29,000 clinical samples from pandemic flu Vx trials
- Conducted 2 IND-enabling tox studies for universal & pandemic flu Vx’s
- Evaluated 2 H7N9 Vx’s in reproductive tox studies

## Ebola/Filovirus
- Screened >25 Filovirus Vx’s and/or dosing regimens; ID’d AD26/MVA as lead
- Evaluated EBOV, SUDV & MARV Vx’s for CoP
- Developed standardized assays (ELISA subclasses, ADCC, immuno-profiling)
- Enhanced or established quality systems at BSL-4 sites
- Developed ferret challenge model and assays
- Meta-analysis of NHP (cyno) control data

## Zika
- Conducted IND-enabling tox studies for 3 Zika Vx’s
- Evaluated VTEU phase 1 (MN assay) and VRC Phase 2 samples (PCR assay)
- Developed standardized assays (Plaque, PRNT, MN, Flow RVP, PCR)
- Evaluated Zika Vx’s and IVIG for immunogenicity and efficacy in NHPs
NIAID Funding Opportunities (sample)

Grants: [https://www.niaid.nih.gov/grants-contracts/opportunities](https://www.niaid.nih.gov/grants-contracts/opportunities)

- RFA-AI-19-028/029: Emerging Infectious Diseases Research centers
- PAR-19-247/248: Research Projects to Improve the Predictive Value of Animal Models in Recapitulating Human Immunity to Influenza Infection and Vaccination (R01 and R21)
- RFA-AI-19-030: Feasibility of Novel Diagnostics for TB in Endemic Countries (FEND for TB) (U01)
- RFA-AI-19-037: Targeted Prevention for Tickborne Diseases (R01)


Questions?
BACK-UP
Preclinical Services Life Cycle

- Contractor conducts study
- Regular progress mtgs held with all stakeholders
- Contractor submits study report to NIAID
- NIAID shares report with ER

Requests Originate:
- ER via Branch PO
- ER via OBRRTR PO or CAP
- OBRRTR PO or CAP

- Contractor submits protocol or proposal
- NIAID reviews
- Protocol discussions include all stakeholders

- Request/Concept Discussed: thumbs up or thumbs down
- NCEA executed
- SRF submitted/Request finalized

- If approved, and TO exists, study request sent to Contractor/option exercised
- If no TO exists, Branch and/or OBRRTR/CAP write new TO, to include SOW for study design
- PD provides input