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

NSTC Conference “Building Bridges for Impacts across the S&T Enterprise”
June 13th, 2019
NIAID & the Biodefense Enterprise
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-NIH funded external requestors

Outbreak response: Leverage PCS

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

Adv. promising candidates & tech

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

Gap filling studies for PD efforts

- 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
DMID Preclinical Services

Suite of service contracts that provide a broad range of assays and capabilities to the extramural community free-of-charge
### 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
QUESTIONS