



# CBRN VACCINE PROGRAMS

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*Resilient People. Healthy Communities. A Nation Prepared.*

# Goals Driven by Program Maturity

- Smallpox & Anthrax programs are the most mature of our vaccine programs
  - Current stockpile capability exists (e.g. AVA and IMVAMUNE)
  - Program emphasis shifts from capability establishment to capability enhancement and sustainment, e.g.,
    - Shelf-life
    - Improved immune response with fewer doses
    - Enhanced manufacturing capacity
    - Simplified route of administration
    - Special populations



# Smallpox Vaccine Program

- Overarching Strategy: Maintain preparedness levels, addressing the needs of at risk individuals with compromised immune system or with atopic dermatitis during a smallpox emergency

## Near-term objectives

1. Stockpile maintenance of liquid frozen IMVAMUNE with transition to lyophilized formulation
2. Completion of activities for licensure of liquid frozen and lyophilized IMVAMUNE

## Future objectives

1. Transition licensed vaccines to SNS for maintenance



**Note: No additional vaccine development programs are planned for smallpox**

# Anthrax Vaccine Program

- Overarching Strategy: Expand BioThrax utility and pursue licensure of next generation vaccine(s) that provide equivalent protection with fewer doses at potentially lower cost

Near-term objectives – focus on enhancements of BioThrax<sup>®</sup>

1. Label expansion for Post-exposure Prophylaxis (Achieved)
2. Expansion of domestic manufacturing capacity (Achieved)
3. Adjuvanted formulation of BioThrax<sup>®</sup> (Nuthrax) currently under advanced development

Future objectives

1. Evaluation and continued development of next generation vaccine candidates that offer transformative improvements

**Note: Vaccine candidates must demonstrate potential to offer USG substantial enhancements over established vaccine for funding consideration or continued investment**



# VHF Vaccine Program

## Near-term objectives

1. BARDA is working with PHEMCE partners to maximize limited funding resources towards accelerating promising monovalent Ebola vaccine candidate products towards licensure
2. Establish an initial response capability for Ebola via stockpiling of monovalent vaccine candidate with PBS funding (FY2017) based on availability of funds

## Future objectives

1. Develop promising vaccine candidates against Sudan and Marburg with emphasis on multivalent or monovalent vaccines
2. Initial objective to advance these products through end of Phase 2 development to facilitate potential stockpiling countermeasures
  - Please see CBRN BAA Area of Interest #1 for information on minimum technical requirements for consideration



# Where do we go from here:

- Address existing gaps in VHF requirements (Marburg and Sudan)
- Potential entry into vaccines for antimicrobial resistance in FY2018 (dependent on CARB funding availability)
  
- Important considerations:
  1. BARDA funds advanced research and development (TRL 7) and offerors are expected to have completed phase 1 clinical study
  2. Monitor FedBizOpps ([Federal Business Opportunities](#)) for issuance of new BAAs or amendments to current BAA (BAA-16-100-SOL-00001 - Research Area #1: Vaccines)

