



CBRN VACCINE PROGRAMS

Daniel Wolfe, Ph.D.
Health Scientist, Vaccine Branch
CBRN Division

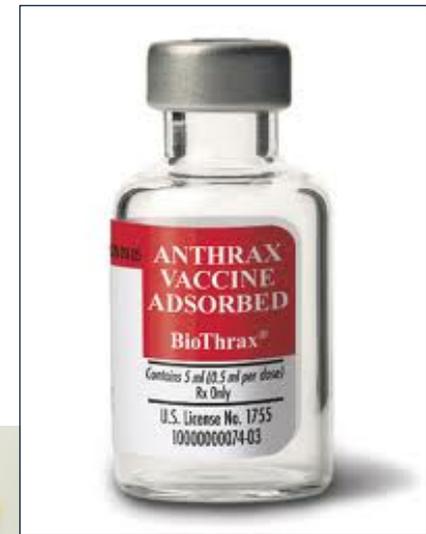
BARDA Industry Day
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CBRN Vaccines: Goals Driven by Program Maturity (1)

Smallpox and Anthrax Programs

- Mature vaccine programs; licensed products and stockpile capabilities exist
- Program emphasis is enhancing and sustaining the capability
 - Operational use and logistics
 - Extended shelf life
 - Reduction of doses needed for protection
 - Protecting special populations





CBRN Vaccines: Goals Driven by Program Maturity (2)

Viral Hemorrhagic Fever Program

- Ebola (*Zaire ebolavirus*) vaccine program matured rapidly through public and private investments
 - Multiple vaccines in Phase 2 and 3 clinical trials
 - Two Project BioShield awards
- Unmet needs remain for *Sudan ebolavirus* and *Marburg virus*



Investigational Use Only



Sudan/Marburg Vaccine Snapshot



Smallpox Vaccine Program

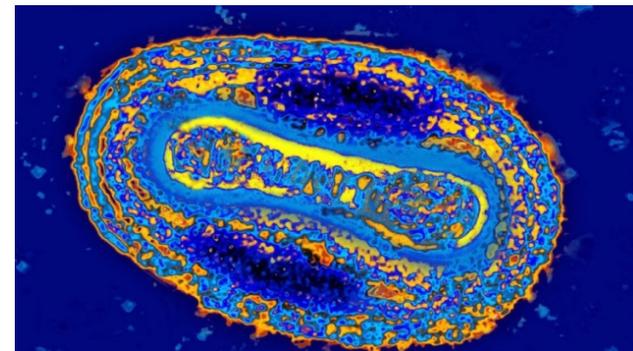
Overarching Strategy

Maintain preparedness levels and address the needs of special populations (immunocompromised individuals) during a smallpox emergency

Problem: Current formulations have limited stability; limited capabilities for immunocompromised individuals

- Near-term objectives:
 1. Maintain stockpile of IMVAMUNE with transition to lyophilized formulation
 2. Complete activities for licensure of liquid frozen and lyophilized IMVAMUNE
- Future objectives:
 1. Transition lyophilized IMVAMUNE to SNS for maintenance

Note: No additional vaccine development programs are planned for smallpox



Credit: Getty Images



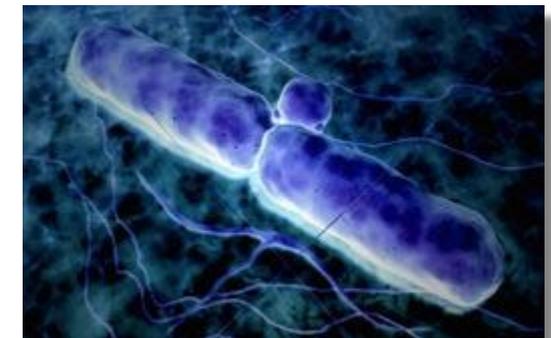
Anthrax Vaccine Program

Overarching Strategy

Expand BioThrax utility and pursue licensure of next generation vaccine(s) that provide equivalent protection with fewer doses

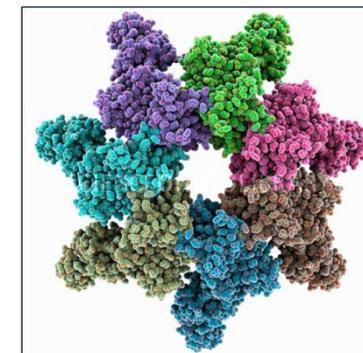
Problem: Current Anthrax vaccine requires 3 doses; only for 18-65 year olds

- Near-term objectives
 1. Enhance utility of BioThrax and AV7909
 2. Evaluate Protective Antigen-based candidates
- Future objectives
 1. Achieve licensure of AV7909
 2. Assess potential single-dose vaccines



<http://www.nature.com/news/2008/080929/full/news.2008.1137.html>

Note: Future investments will only include single-dose vaccines but no proposals will be sought at this time



<http://www.sciencephoto.com/media/473072/view>



Viral Hemorrhagic Fever Vaccine Program

Overarching Strategy

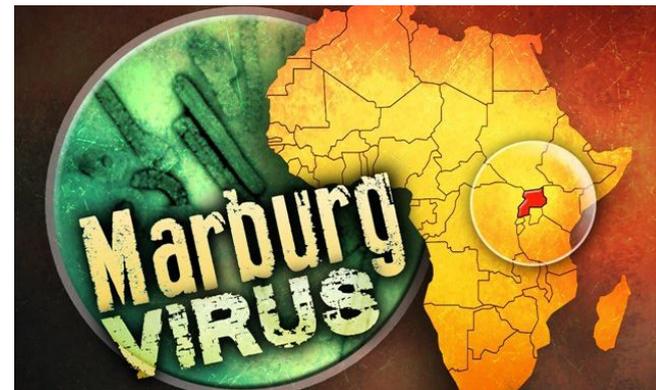
Enhance protective capabilities for Ebola while establishing a portfolio of Sudan and Marburg candidates to be evaluated in clinical studies

Problem: No licensed vaccines are available; pipeline is limited for Sudan and Marburg

- Near-term objectives
 1. Achieve licensure for Ebola vaccine(s)
 2. Establish a portfolio of Sudan and Marburg vaccines
- Future objectives
 1. Evaluate utility of monovalent versus multivalent approaches
 2. Down-select Sudan/Marburg candidates to continue towards licensure



<http://ebolaelvirus.blogspot.com/>



<http://pressug.com/marburg-outbreak-update150-cases-followed-one-confirmed-one-probable-case/>



Future Directions

Key Gaps and Potential Paths Forward

1. Address existing gaps in VHF requirements (Sudan and Marburg) including:
 - a) Candidate development
 - b) Animal models
 - c) Critical assays
2. Enhance the utility of current vaccines; operational use, special populations, etc.
3. Identify opportunities in which vaccines can be used to target antimicrobial resistant threats:
 - a) Reduce morbidity and mortality
 - b) Reduce the prevalence of resistant serotypes/strains
 - c) Reduce the need for antibiotics

Note: Monitor FedBizOpps (Federal Business Opportunities) for issuance of new BAAs or amendments to current BAA





Online Resources

<https://www.medicalcountermeasures.gov/home.aspx>

- Portal to BARDA: Register to request a **TechWatch** meeting

<https://www.fbo.gov/> (“FedBizOpps”)

- Official announcements and info for all government contract solicitations

<https://www.usajobs.gov/>

- Join the team!

<https://www.phe.gov/about/BARDA/Pages/default.aspx>

- Program description, information, news, announcements

