CBRN Vaccine Programs

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CBRN Vaccines: Advanced Development and Procurement of Vaccines for CBRN Threats

https://www.pbs.org/wgbh/frontline/article/the-anthrax-attacks-10-years-later/


https://www.staywellworld.org/single-post/2017/10/10/SMALLPOX-AN-ERADICATED-VIRUS


CBRN Vaccines: Advanced Development and Procurement of Vaccines for CBRN Threats

Pipeline of Promising Early Stage Vaccine Candidates

Successful Transition of R&D Programs to Late-Stage
CBRN Vaccines: Current Programs
Smallpox, Anthrax, and Ebola Vaccines

FOCUS

• Mature vaccine programs; products licensed and/or nearing licensure

STRATEGY

• Expand existing capabilities and enhance sustainability
  ▪ Protecting special populations
  ▪ Improving operational logistics and life cycle costs

https://www.rxlist.com/menhibrix-drug.htm

CBRN Vaccines: Smallpox Vaccine Program

Overarching Strategy

Maintain preparedness to address the needs of special populations during a smallpox emergency

- **Near-term objectives:** Licensure of liquid frozen MVA vaccine; remaining activities to support lyophilized formulation
- **Future objective:** Transition stockpile to lyophilized MVA vaccine

Highlight: Pre-EUA in place to address the needs of special populations
CBRN Vaccines: Anthrax Vaccine Program

Overarching Strategy

Expand anthrax vaccine utility and pursue licensure of next generation vaccine(s) with improved operational logistics and life cycle costs

- **Near-term objectives:** Expand use of BioThrax and pre-EUA of AV7909; Evaluate Protective Antigen-based and single-dose candidates

- **Future objective:** Achieve licensure of AV7909; enhance sustainability and logistics

Highlight: Ongoing clinical study to help inform use of vaccine in senior population

https://globalbiodefense.com/2016/05/04/anthrax-infections-dod-anthrax-vaccine-policy/
CBRN Vaccines: Ebola Vaccine Program

Overarching Strategy

Develop and stockpile vaccines to prepare for Ebola outbreaks

- **Near-term objectives:** Complete late-stage development activities of Ebola vaccines(s)
- **Future objective:** Initiate stockpile and achieve licensure

Highlight: Interagency support and coordination has rapidly advanced candidates into Phase 3

http://ebolaelvirus.blogspot.com/

Investigational Use Only
CBRN Vaccines: New Program Areas
Sudan ebolavirus, Marburg virus, and Bacterial Threats

**FOCUS**
- Establish vaccine programs in areas with limited pipelines

**STRATEGY**
- Emphasize IND-enabling studies and progression into the clinic
  - Non-clinical efficacy proof-of-concept will be entry threshold
  - Focus on critical pathway to clinical development

Sudan/Marburg Vaccine Pipeline Snapshot

https://www.youtube.com/watch?v=5AVmRYYqAgg

https://www.youtube.com/watch?v=SAVMRYqAgg
CBRN Vaccines: Marburg and Sudan Vaccines

Establish a portfolio of Sudan ebolavirus and Marburg virus vaccine candidates

• **Near-term objectives**: Support early stage programs for monovalent Sudan and Marburg vaccines
• **Future objective**: Down-select Sudan/Marburg candidates to support to licensure

[Links to relevant articles and resources]
Establish a portfolio of vaccines against bacterial threats

- **Near-term objectives**: Assess potential for pre- and post-exposure prophylaxis vaccines against *Burkholderia* species
- **Future objective**: Expand portfolio to address urgent antimicrobial-resistant bacterial pathogens

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- **Hazard level: Urgent**
  - *Clostridium difficile*
  - Carbapenem-R Enterobacteriaceae (CRE)
  - Cephalosporin-R Neisseria gonorrhoeae

- **Hazard level: Serious**
  - MDR *Acinetobacter*, MDR *Pseudomonas*, ESBL GNRs
  - MRSA, VRE, Drug-R *pneumococcus*, Drug-R Enteric GNRs
  - MDR and XDR *TB*, Azole-resistant Candida

- **Hazard level: Concerning**
  - *Vancomycin-R Staphylococcus aureus*
  - *Macrolide-R group A streptococci*
  - *Clindamycin-R group B streptococci*
CBRN Vaccines: Additional Services Available through BARDA

CBRN Vaccines needs a pipeline of candidates for *Sudan ebolavirus*, *Marburg virus*, and Bacterial Threats

Available resources include:

- Manufacturing
- Non-clinical Services Network
- Clinical Services Network
- Regulatory and Quality Affairs

https://ciadm.tamhsc.edu/
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Broad Agency Announcement
BAA-18-100-SOL-00003

How to contact BARDA

medicalcountermeasures.gov/home.aspx
Portal to BARDA: Register to request a TechWatch meeting!

www.fbo.gov/ ("FedBizOpps")
Official announcements and info for all government contract solicitations

https://www.phe.gov/about/BARDA/Pages/default.aspx
Program description, information, news, announcements

www.drive.hhs.gov
DRIVE questions

https://www.usajobs.gov/
Join the team!