



BARDA INDUSTRY DAY

CBRN Vaccine Programs

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October 29, 2018

October 29-30, 2018 | Grand Hyatt • Washington, D.C.



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



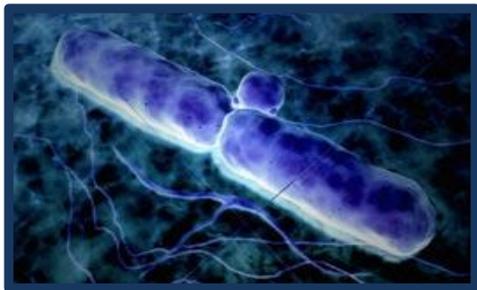
<https://www.pbs.org/wgbh/frontline/article/the-anthrax-attacks-10-years-later/>



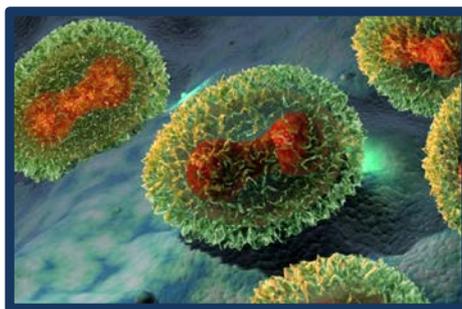
<https://www.newsweek.com/smallpox-drug-will-be-stockpiled-us-government-case-bioterrorism-attack-1028086>



<https://www.npr.org/sections/goatsandsoda/2018/08/27/641536981/a-dangerous-twist-to-the-latest-ebola-outbreak>



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



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



<https://phys.org/news/2017-09-breakthrough-rapid-mass-screening-ebola.html>

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

Pipeline of Promising Early Stage Vaccine Candidates

PFE*nex*

 altimmune

Successful Transition of R&D Programs to Late-Stage

janssen 

PHARMACEUTICAL COMPANIES
OF *Johnson & Johnson*

 **MERCK**

 emergent
biosolutions™


BAVARIAN NORDIC

CBRN Vaccines: Current Programs

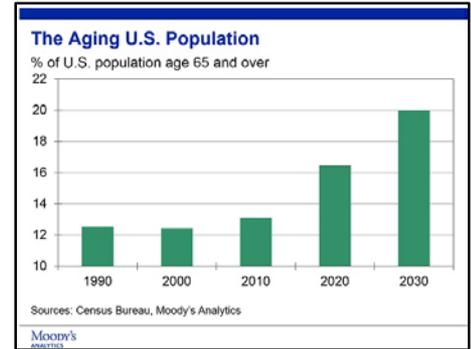
Smallpox, Anthrax, and Ebola Vaccines

FOCUS

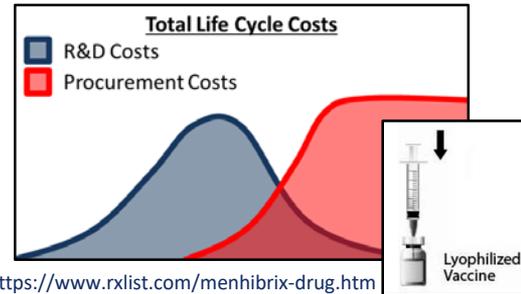
- Mature vaccine programs; products licensed and/or nearing licensure

STRATEGY

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



<https://www.thestreet.com/story/13068987/1/the-aging-us-population-could-stymie-future-job-growth.html>



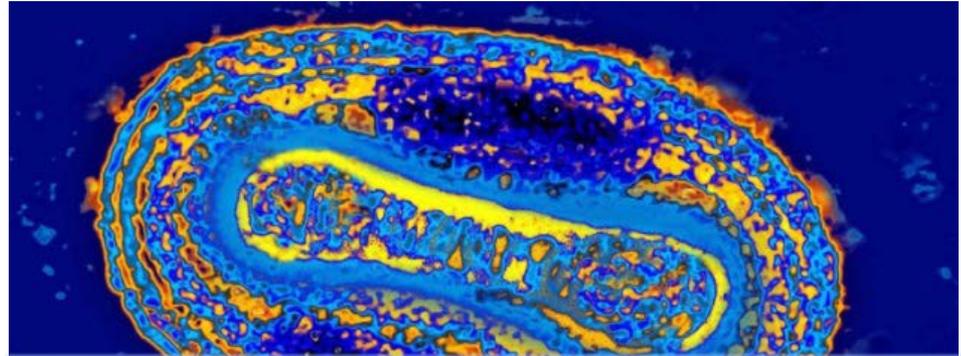
<https://www.rxlist.com/menhibrix-drug.htm>

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



Credit: Getty Images

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



ANTHRAX



<https://globalbiodefense.com/2016/05/04/anthrax-infections-dod-anthrax-vaccine-policy/>

Participate in the B-SAFE Study

Local doctors are studying investigational vaccines for Anthrax. The B-SAFE study is enrolling now to learn more about two Anthrax vaccines.

You cannot get Anthrax from participating in this study.

You may qualify for this study if you are:

- 18-50 years of age -OR- 65 years of age or older
- In good general health

Qualified volunteers may receive:

- No-cost investigational vaccine for Anthrax
- No-cost study-related care from a local doctor
- Reimbursement for travel

For more information about this study please call:



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 vaccine(s)
- **Future objective:** Initiate stockpile and achieve licensure

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



CBRN Vaccines: New Program Areas

Sudan ebolavirus, Marburg virus, and Bacterial Threats

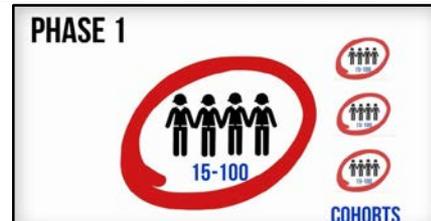
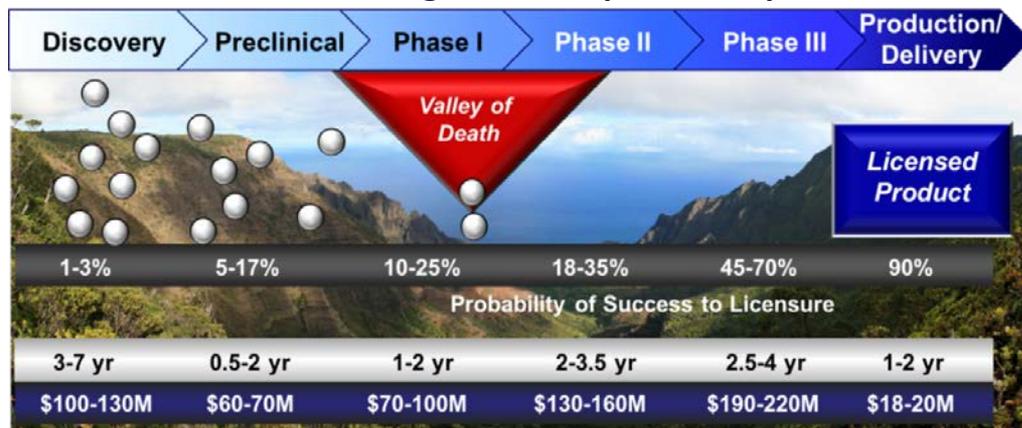
FOCUS

- 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



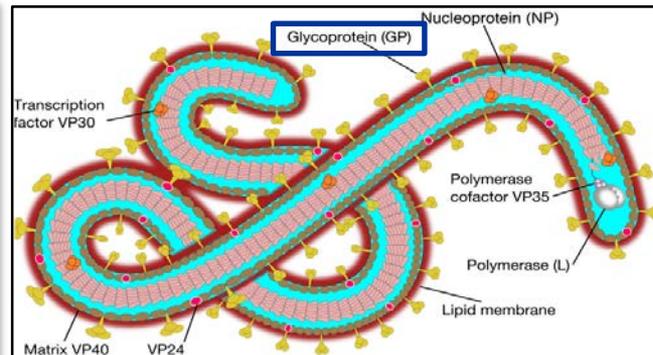
<https://www.youtube.com/watch?v=5AVmRYYqAgg>

CBRN Vaccines: Marburg and Sudan Vaccines

Overarching Strategy

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



<http://journal.frontiersin.org/article/10.3389/fmicb.2015.00257/full>

ktn NEWS
MARBURG VIRUS DISEASE
UGANDA OUTBREAK

17TH OCTOBER 2017
Marburg confirmed at Uganda Virus Research Institute
As Of 28 October 2017
5 cases reported
The first case: Male in his 30s

The news report includes a photograph of a laboratory setting with petri dishes and a microscope, showing the results of a Marburg virus outbreak in Uganda.

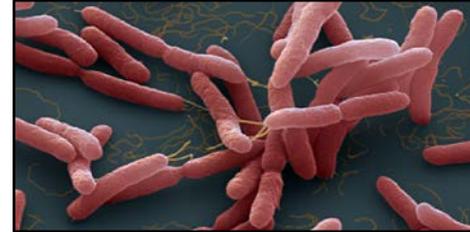
<http://www.cdc.gov/vhf/ebola/outbreaks/history/distribution-map.html>

CBRN Vaccines: Bacterial Threats

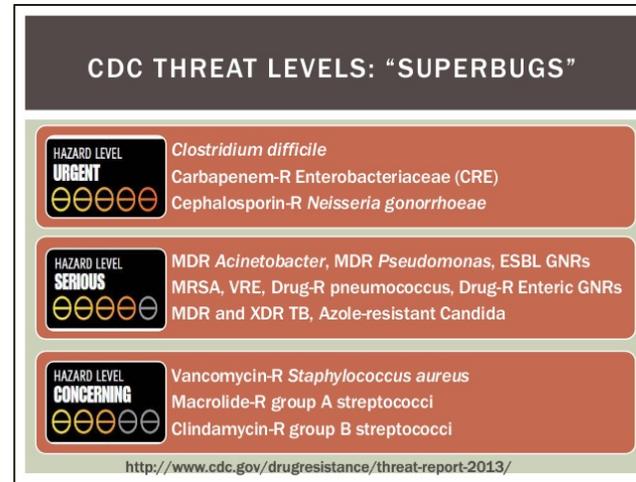
Overarching Strategy

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



<https://www.npr.org/sections/goatsandsoda/2016/01/11/462416728/this-germ-can-live-decades-in-distilled-water-kill-humans-in-48-hours>



CBRN Vaccines: Additional Services Available through BARDA



<https://ciadm.tamhsc.edu/>

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



Participate in the B-SAFE Study!

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- OB- 66 years of age or older
- In good general health

Qualified volunteers may receive:

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- No-cost study-related care from a local doctor
- Reimbursement for travel

To learn more about this study please call: XXX-XXX-XXXX

CBRN Vaccines Team

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Broad Agency Announcement BAA-18-100-SOL-00003

<https://www.fbo.gov/index.php?tab=documents&tabmode=form&subtab=core&tabid=37d798db116ff9367361eff321d1d7d9>

How to contact BARDA



Medical
Countermeasures.gov

[medicalcountermeasures.gov/home.aspx](https://www.mediccountermeasures.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
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