



CHEMICAL/BIOLOGICAL/ RADIOLOGICAL/NUCLEAR

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BARDA's Industry Day

Resilient People. Healthy Communities. A Nation Prepared.

Overview

- Successes
- Challenges
- What's new
- Emphasis moving forward



Successes

- Three additional programs supported by ASPR/BARDA have achieved FDA licensure/approval
 - Anthrax antitoxin to treat individuals exposed to anthrax (Elusys)
 - Licensure of a new manufacturing facility to manufacture anthrax vaccine (Emergent)
 - Licensure of anthrax vaccine for Post-exposure prophylaxis (PEP) (Emergent)
 - Submission of NDA for a BSA (Cempra)
- ASPR/BARDA has now supported 14 MCMs that have been added to the SNS
- Launched CARB-X
- Issued decontamination guidance on PRISM



Successes

- Numerous programs, under ARD, are advancing through clinical development
 - Setting them up for potential transition to late-stage development and potential procurement under PBS in the coming years
- Expanded BSA portfolio under two, new OT
- New strategies for the Rad/Nuc and Chem programs
 - Treat the pathologies/injuries and not the specific threat agent
 - Many pathologies that result from exposure to Rad/Nuc or Chem agents are similar to pathologies seen in more common diseases and therefore their may be products under development for commercial indications that could be applicable to injuries resulting from exposure to Rad/Nuc or Chem agents



Successes

- We revised the BAA to streamline the application process and aligned all BAAs with respect to quarterly submissions
- Working closely with:
 - FDA's PHSAT to develop animal models for rad/nuc and chemical threats
 - SNS as programs transition from PBS to SNS in the coming years
- Engaging with end-users and professional societies
 - IDSA
 - ABA
 - RITN
 - AABB



Challenges Moving Forward

- Funding
 - BARDA's need under ARD exceeds funding
 - FY2016: \$415M for ARD, \$107M for CARB, \$510M for PBS, \$117M for Ebola efforts
 - FY2017 will most likely be a CR, not a bad thing considering the increased funding received in FY2016 - uncertain of additional Ebola funding from the supplemental
- Timing of Funding under a CR
 - Receive approximately $\frac{1}{4}$ of funding in Q1 but is not provided on October 1, usually provided in late November/ early December
 - Remaining funds are made available once a full-year CR or budget is passed
 - We are trying to move up release of potential solicitations under PBS to Q1 but funding needs to be available for release of these solicitations



Challenges Moving Forward

- Sustainment – This is not simply an issue for BARDA but also the PHEMCE
 - Sustaining companies after the initial procurements
 - Trying to be a good business partner even under conditions where budgets may not allow
 - How many candidates to maintain and how much to procure to sustain our partners while trying to balance competing priorities for a limited budget
 - Working more closely with the SNS as programs transition from PBS support to SNS maintenance



Challenges Moving Forward

- Phase IV post marketing commitments/requirements
 - As products are licensed/approved under the animal rule this issue has become a high priority for the sponsors and the PHEMCE
 - PHEMCE has established a Monitoring and Assessment IPT to address this issue
- Coming change in Administration
 - Uncertain what the priorities of the new Administration will be
- PAHPRA expires at the end of FY2018
 - Uncertain what funds will be available beyond FY2018



What's New?

- Revised the Broad Agency Announcements
 - Revised system for review of WP and Proposals – two tiered system
 - Aligned submission deadlines across all BARDA BAAs
- BARDA Strategic Plan for FY2017-22 has been drafted and will be released in the coming months
- PHEMCE Strategy and Implementation Plan has been updated and will be released in FY2017
- BARDA is emphasizing total-life cycle management costs to inform out-year budget planning and the MYB



Emphasis Moving Forward

- The following portfolio of programs are mature:
 - Anthrax
 - Smallpox
 - Botulism
- While we maintain market surveillance, we don't anticipate adding additional programs to these portfolios beyond what is already supported unless there is a significant advantage to:
 - Dosing and administration
 - Life-cycle management costs
- Programs that want to be considered need to truly be in advanced development



Emphasis Moving Forward

- The following portfolio of programs are still seeking promising candidates
 - Chemical threats/injuries
 - Rad/Nuc
 - Viral Hemorrhagic Fever viruses – Marburg and Sudan
- For the Chem and Rad/Nuc portfolios we are able to evaluate candidates that treat the injuries from exposure to the agents and may have a potential commercial market
- VHF viruses – we have several candidates, vaccines and therapeutics, under development for Ebola but have yet to invest in candidates for Marburg and Sudan

