



SUSTAINABLE PREPAREDNESS FOR ESTABLISHED THREATS: CHALLENGES & STRATEGY

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Resilient People. Healthy Communities. A Nation Prepared.

CBRN Material Threats

Agent	Disease
<i>Bacillus anthracis</i>	Anthrax
<i>Burkholderia mallei</i>	Glanders
<i>Burkholderia pseudomallei</i>	Melioidosis
<i>Botulinum toxins</i>	Botulism
<i>Ebola virus</i>	Ebola virus disease
<i>Francisella tularensis</i>	Tularemia
<i>Marburg virus</i>	Marburg virus disease
<i>Rickettsia prowazekii</i>	Typhus
<i>Variola virus</i>	Smallpox
<i>Yersinia pestis</i>	Plague
Radiological and nuclear agents	
Cyanides	
Volatile nerve agents	



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Project BioShield Acquisitions

Threat	Product	Award Date
Anthrax	AVA vaccine	2007
	Nuthrax Vaccine	2016
	Anthrax Immune Globulin	2005
	Raxibacumab	2005
	Obiltoxaximab	2016
Botulinum Toxins	Heptavalent BAT	2006
Smallpox	MVA vaccine	2008
	Tecovirimat	2011
Radiological/Nuclear	Potassium iodide	2005
	Calcium/Zinc DTPA	2005
	Neupogen	2013
	Neulasta	2016
	Leukine	2013
	DxTerity Biodosimetry	2016
	MRIGlobal Biodosimetry	2016
Thermal Burns	Silverlon Dressings	2015
	NexoBrid Topical Gel	2015
	StratGraft Skin Substitute	2015
	ReCell	2015
Volatile nerve agents	Midazolam	2013

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Project BioShield Acquisitions

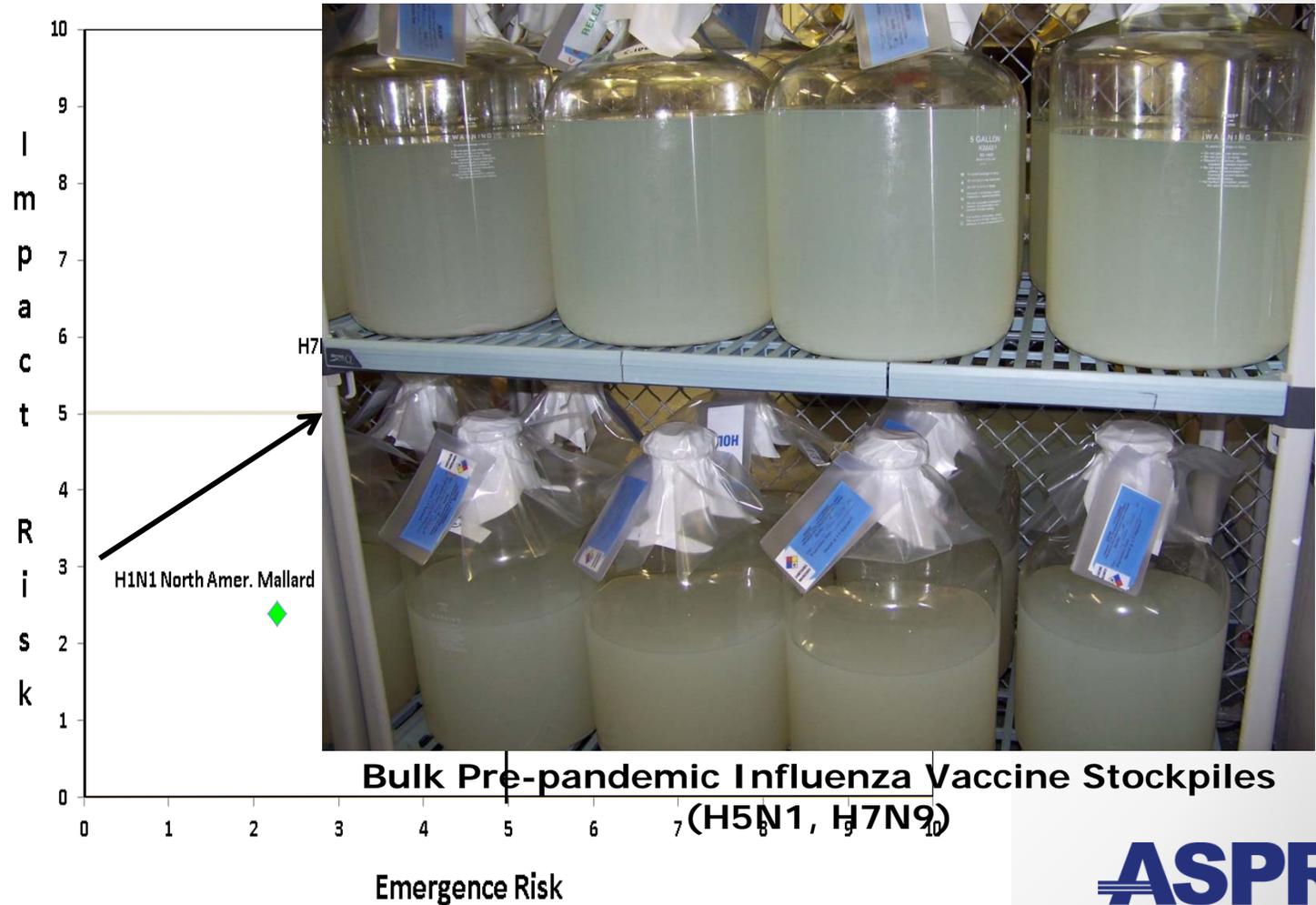
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Known and Evolving Flu Viruses

Influenza Risk Assessment Tool



Infrastructure / Response Capability

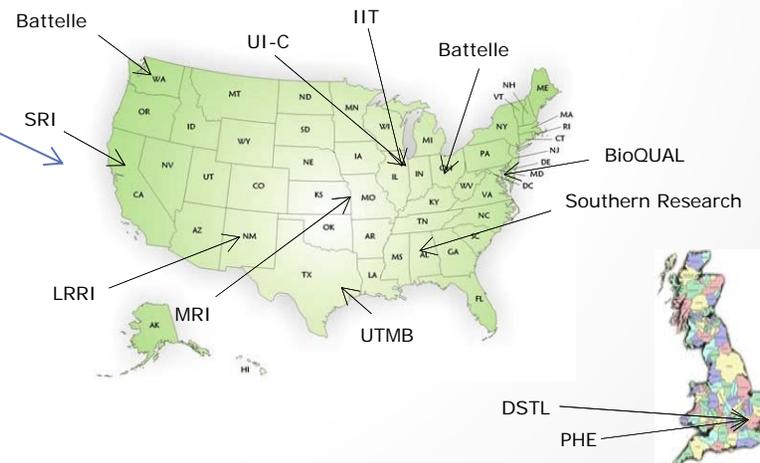
National MCM Response Infrastructure



CENTERS FOR INNOVATION IN ADVANCED DEVELOPMENT AND MANUFACTURING (CIADM)



Nonclinical Development Network



BARDA's Commitment

- Working closely with end users to define desired product attributes and identify remaining gaps
- Maintaining and where appropriate expanding the portfolio of MCMs against CBRN threats, EIDs, and pandemic influenza to meet USG goals
- Leveraging BARDA's core service capabilities to accelerate product development
- Supporting the development of MCMs suitable for use in special populations such as children, pregnant women, the elderly, and persons with compromised immune systems.



Rigorous Portfolio Management

2016 portfolio continues high-value trend established in prior reviews; continuing investments assessed as higher value/higher risk in 2015 have maintained their feasibility position.

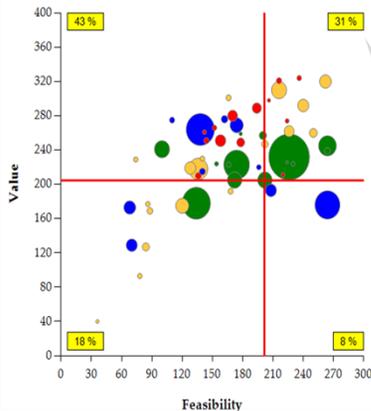
Value Note:

The aggregate value axis is composed of the Meeting Strategic Goal, Emergency Threat Impact, Building Enduring Capability, Multi-Functionality, Innovation, and Operational Capacity metrics

Feasibility Note:

The aggregate feasibility axis is composed of the Company Experience, Product, Regulatory, and Manufacturing metrics

2016 Evaluated R&D Portfolio
55 Projects, \$2.53B



Program Performance ¹	
A	100%
B	100%
C	100%
D	79%
E	76%
F	55%
G	52%
H	50%
I	24%
J	7%

¹Programs not listed have no investment in upper-right

% All Evaluated Projects

Quadrant Analysis

# of Evaluated Projects	
26 (2 New)	17 (2 New)
10 (1 New)	2 (0 New)
R&D Obligated (\$M)	
\$1,094	\$795
\$444	\$197

TLCC Tool

Project Name	Agency/Company	Compound	Project Lead	Division	Branch	Matrix Team
Year	Year	Year	Year	Year	Year	Year

Project Level: TLCC and Cost Avoidance Reporting

Project Name	Agency/Company	Compound	Project Lead	Division	Branch	Matrix Team
Year	Year	Year	Year	Year	Year	Year

Engaging Sponsors on TLCC

BARDA Cost Avoidance Register

By Division	TLCC Cost Avoidance Reflow	Improvement	Cost Savings Available	Total
Division	Year	Year	Year	Year



Supporting Sustainable Products

- Promoting flexible, multiproduct platforms and countermeasures with broad-spectrum activity that can achieve commercial viability
- Supporting product improvements that increase yield or potency, lengthen shelf-life, or simplify storage
- Repurposing approved drugs to address medical countermeasure requirements
- Supporting the development of diagnostic assays compatible with existing commercial platforms and/or that allow for greater precision in MCM dispensing
- Exploiting less expensive alternatives to traditional stockpiling, including vendor-managed inventory and the stockpiling of precursor products.

