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Resilient People. Healthy Communities. A Nation Prepared.

Biodefense MCM History

- Project BioShield Act (2004)
- Pandemic & All-Hazards Preparedness Act (2006)
- Medical Countermeasure Review (2010)
- Pandemic & All-Hazards Preparedness Reauthorization Act (2013)
- PHEMCE Strategy & Implementation Plan (2015)



BARDA's Commitment to Medical Countermeasure Development

Support advanced development of and make available medical countermeasures for CBRN threats, pandemic influenza, and emerging infectious diseases by transitioning MCM candidates from early development across the "Valley of Death" into advanced development to regulatory approval









Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)



PHEMCE Mission Components PHEMCE Mission Components HHS PHEMCE Agencies Non-HHS PHEMCE Agencies Non-Federal Stakeholders

cronyms HEMCE: Public Health Emergency Medical Countermeasure Enterprise HS: Department of Homskand Security DD: Department of Defense SDA: U.S. Department of Agriculture

IPP: Assistant Scientary for Preparedness and Response IRDA: Blomedical Advanced Research & Development Authority DC: Centers for Diseases Control and Prevention Development Pour Advanced Inc.





Requirements

- "Product-Specific Requirements for Medical Countermeasures to Cutaneous Injury from a Nuclear Detonation" Issued by the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and the Radiological and Nuclear Threats Integrated Program Team; August 2010
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More Than Just a Funding Agency

BARDA provides technical support to our contractors for all aspects of the drug development process:

- Collaborative management
- Subject Matter Experts with Pharma experience Advice on experimental, non-clinical, and clinical study design
 - Regulatory experience with MCM issues including animal rule
- Integration with other government MCM-focused agencies
 Contact with MCM-focused offices at FDA

 - Collaboration with DoD medical countermeasure programs

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BARDA Core Services
 Critical Assistance to MCM Developers

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Envisioning a Complete MCM Portfolio

Multiple threat dimensions and timeframes

		Field Care (First 72 hours)	Definitive Care (After 72 hours)
4.4	Acute Radiation Syndrome and Trauma	HS-ARS	HS-ARS
		GI-ARS	GI-ARS
		Pulmonary radiation injury	Pulmonary radiation injury
		Cutaneous injury	Cutaneous injury
		Trauma	NA
. Alex	Thermal Burns	Thermal Burns	Thermal Burns
	Decorporation	Isotope-specific:	Isotope-specific :
		Co-60, Po-210, Cs-137, U-235, Sr-90, Pu-239 I-131, Am-241, Ir-192, etc.	Co-60, Po-210, Cs-137, U-235, Sr-90, Pu-239 I-131, Am-241, Ir-192, etc.





Enabling Community Resiliency

Improving Emergency Response



New Uses for Common Medicines Ensuring availability of lifesaving medicines

Our goal is to improve health outcomes for all victims of chemical exposure L ASPR

Near Term Focus Areas

- Pulmonary Injury from Chlorine and Vesicants Commercial Indications: Pulmonary Edema, Inflammation, Fibrosis, COPD
- Anti-seizure drugs for nerve agent victims whose seizures are refractory to treatment with benzodiazepines Commercial Indications: Refractory seizure, status epilepticus,
- epilepsy
- Cyanide Treatments- Improved Ease of Use
- . Standardized Animal Models for Efficacy Testing



Striving to Find Chemical Threat Indications for Common Drugs Midazolam for Nerve Agent Exposure MERIDIAN Prizer Silverlon[®] Wound Dressing for Sulfur Mustard Burns Argentum Medical Alteplase [®] for Sulfur Mustard Inhalation University of Colorado Bodar | Calvada Barray | Dense | Arastada Messada Caresa ASPE

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BARDA TechWatch Program

- Forum for discussion about stakeholder's technologies/products and BARDA's interests and programs in seminar format at BARDA's offices in Washington
- Opportunity to receive feedback from BARDA Program and Technical staff . Specific direction about stakeholder's plans cannot be given
- Limitations .
 - Generally cannot be held while requestor has a proposal under review by BARDA
 Generally cannot be held to discuss topics related to an acquisition under an open RFP
 - Generally can discuss projects that may fall under an Area of Interest of an open BAA Allow ~6 weeks to schedule

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Please let the relevant PO/branch chief know



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- BARDA Broad Agency Announcement (BAA) Advanced Research and Development of Chemical, Biological, Radiological, and Nuclear Medical Countermeasures (CBRN)
 Vaccines
 Aradwarchineat Medical Countermeasures
 Aradwarchineat Medical Countermeasures
 S. Chemical Threat Medical Countermeasures
- 2. Antimicrobial Drugs
 3. Chemical Diagnostics Tools
 Advanced Development of Medical Countermeasures for Pandemic Influenza
 (FLU)
 1. Personal Protective Equipment
 4. Influenza Therapeutics ь.

- 1. Personal Protective Equipment
 2. Full-Feature Continuous Ventilators
 3. Clinical Text Systems and Diagnostic Tools
 5. Influenza Vaccines
 Cence and Technology Platforms Applied to Medical Countermeasure
 Development (SST)*
 1. Pipeline acceleration and evaluation of candidate vaccines and therapeutics.
 2. Product improvements to enhance safety, effect, ease of use, and manufacturability of MCM.
 3. Product repurposing to treat novel and emerging pathogens.
 5. Total Section 2. Sec

- 4. In vitro diagnostic platforms for the rapid diagnosis of human infection.
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Questions? www.medicalcountermeasures.gov Potal to BARDa Vew BAA proteities Octact Us Mary Homer Chief, Chemical MCMs 202-205-8043 Judith.Levelphihs.gov Mary Homer Chief, Rad/Nuc MCMs 202-205-8604 Mary Homer@hhs.gov Tom Hu Project Officer, Chemical MCMs 202-205-802 Jam.Hu@hhs.gov