



Biomedical Advanced Research and Development Authority Radiological Nuclear Countermeasures Portfolio

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Biomedical Advanced Research and Development Authority (BARDA)

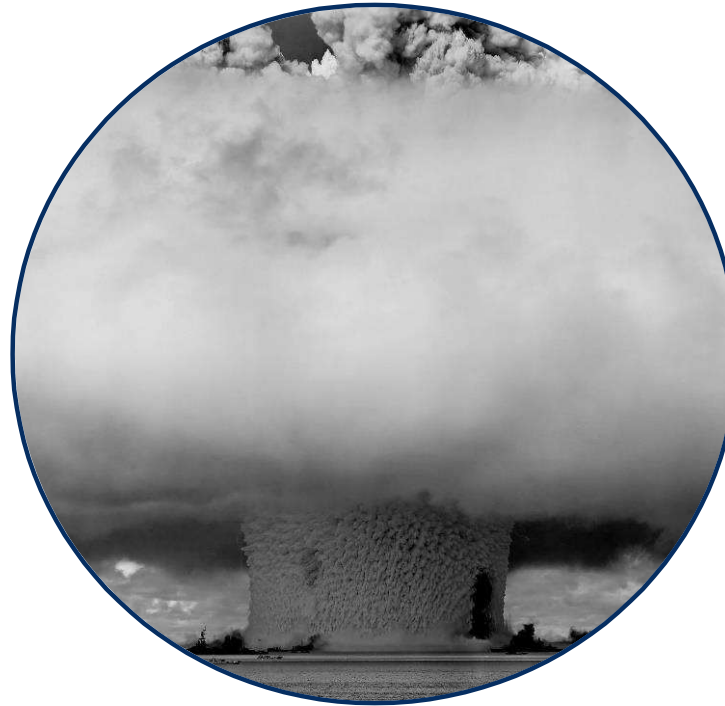
The Hemostatic Resuscitation and Trauma Induced Coagulopathy Conference; Pittsburgh, PA;
October 12, 2022

UNCLASSIFIED

Radiological and Nuclear Threat Landscape



Nuclear Power Plant



Nuclear detonation



Radiological Dispersal Device

The BARDA Model

BARDA develops and makes available medical countermeasures (MCMs) by forming unique public-private partnerships to drive innovation off the bench to the patient to save lives.



Flexible, nimble authorities

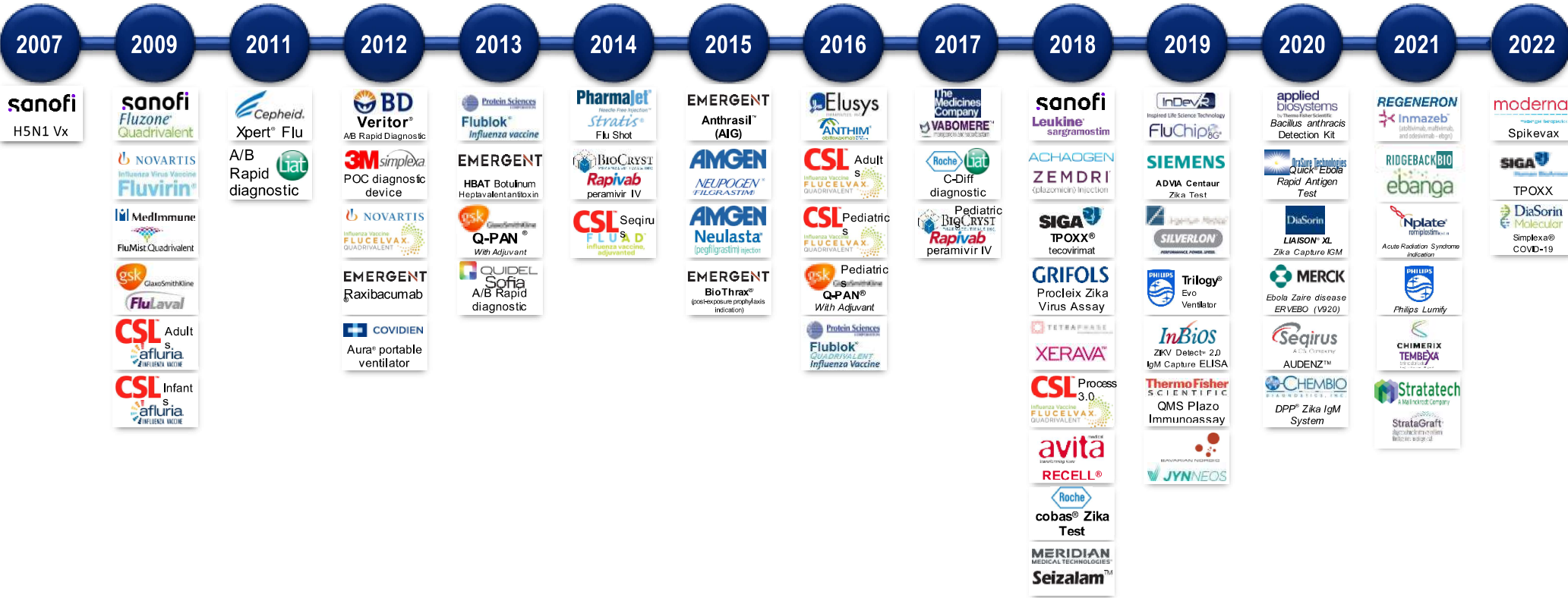
Multi-year funding

Cutting edge expertise

Facilitate partnerships

Promote innovation

64 FDA Approvals, Licensures, and Clearances



CBRN Mission

Make Available at Least One Countermeasure for all CBRN Material Threats



Invest in MCMs to treat the injury, not the threat



Develop innovative MCMs for unknown threats



Deliver novel MCMs against bacterial and viral threats

Project BioShield: A Commitment



■ ≥1 product procured
■ 1 product procured
■ BARDA is developing MCM(s)

30

Products Supported

25

New Products Procured

25

CBRN Approvals, Licensures, and Clearances

Radiological and Nuclear Threat Landscape



Nuclear Power Plant



Nuclear detonation



Radiological Dispersal Device

Operational Resources and Medical Expertise



10kT Detonation

Two major metropolitan areas



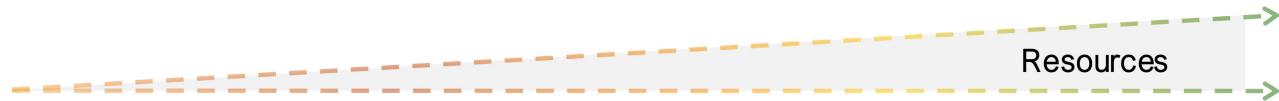
Field care



Enroute



Definitive

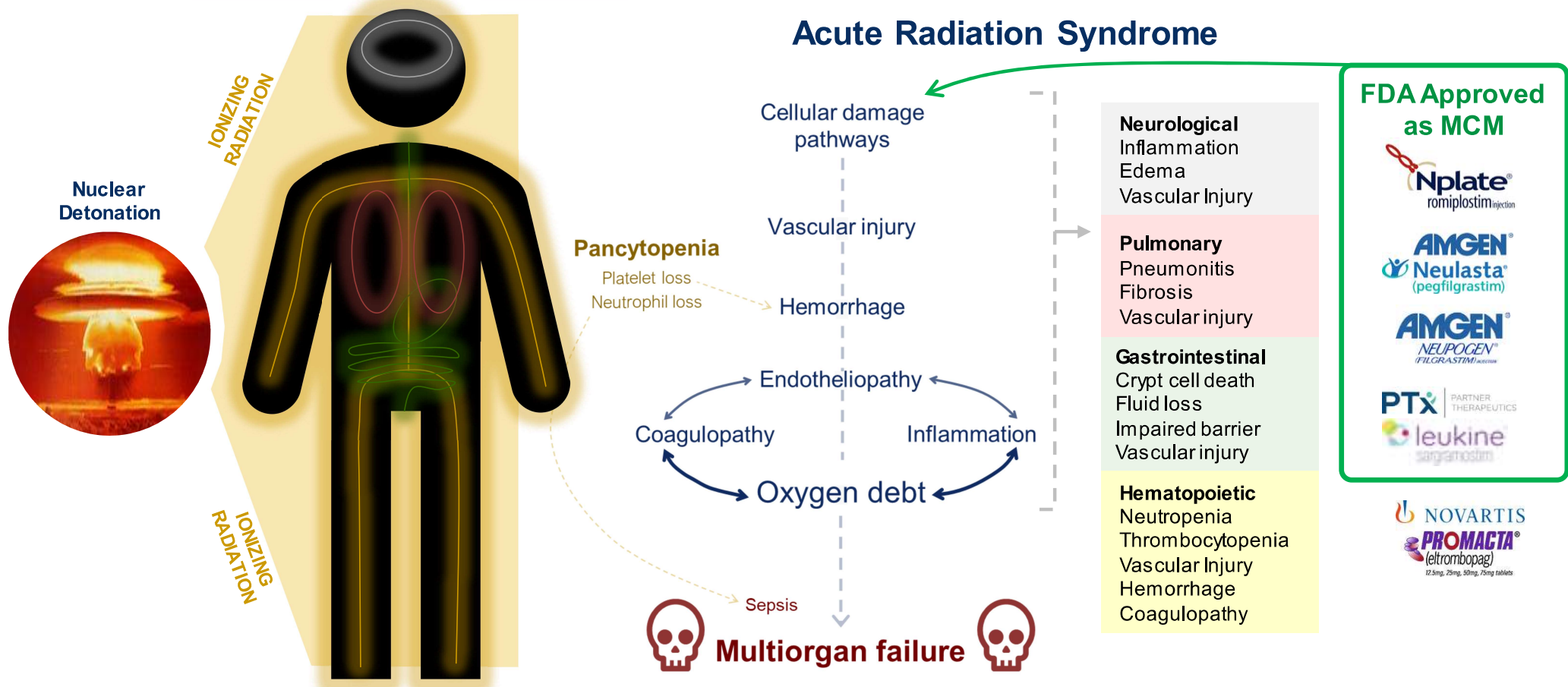


Operational needs

- > Medical provider familiarity with product
 - > Limit cold chain reliance
 - > Improve ease of use

Radiological and Nuclear Threats and Injuries

Exposure – Penetrating Radiation

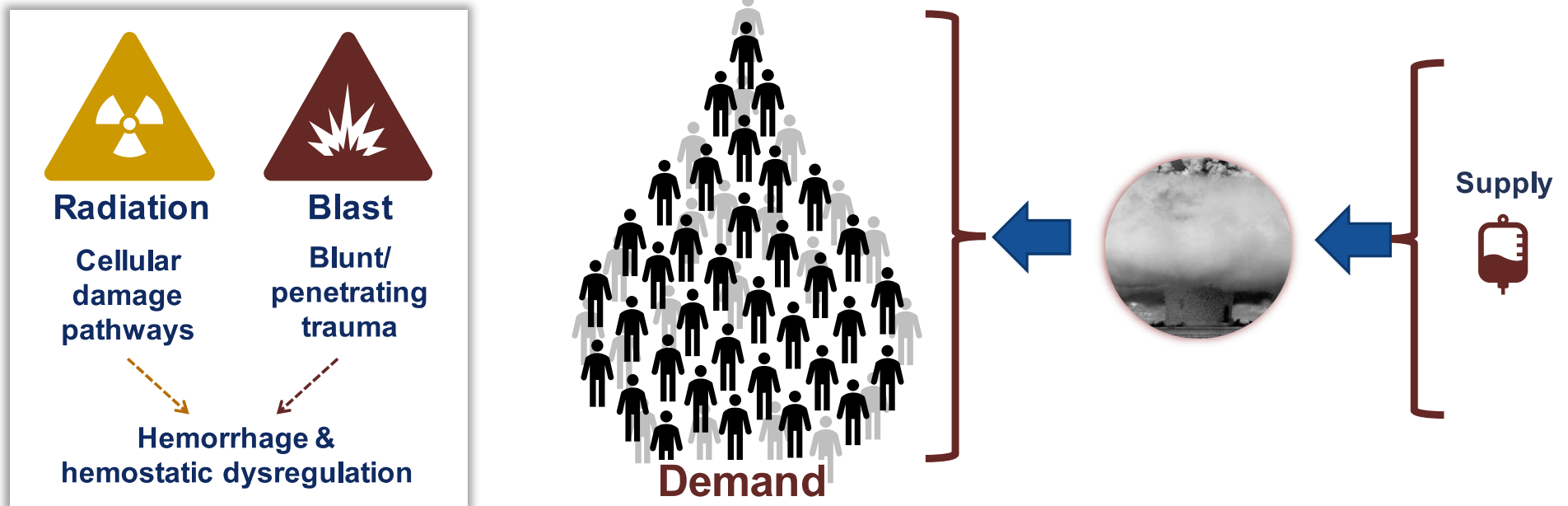


FDA Approved as MCM

- Nplate**
romiplostim injection
- AMGEN**
Neulasta (pegfilgrastim)
- AMGEN**
NEUPOGEN (FILGRASTIM) mesoform
- PTx** | PARTNER THERAPEUTICS
leukine sargamostim

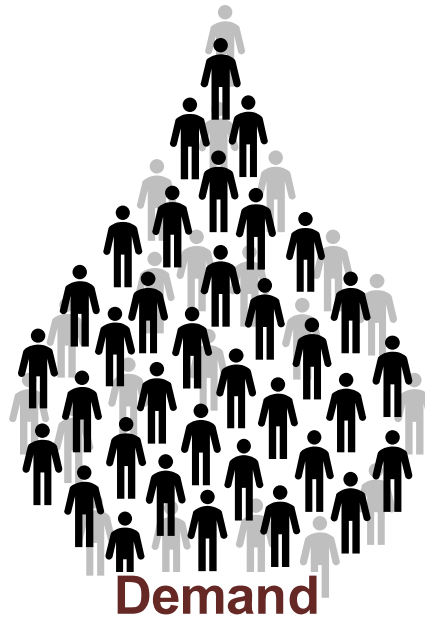
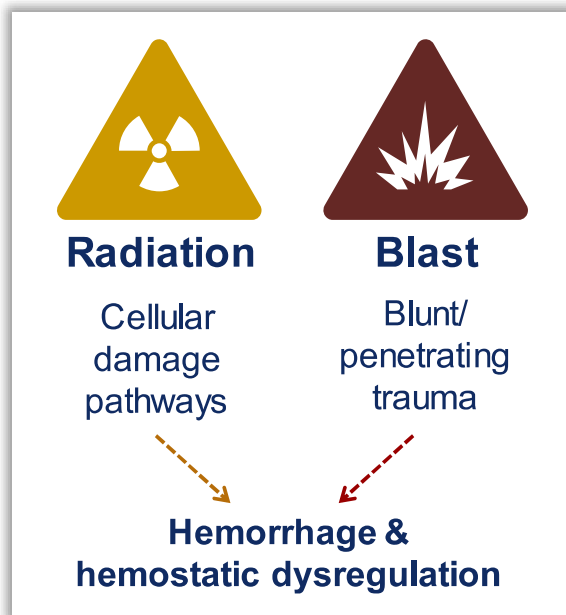
NOVARTIS
PROMACTA
(eltrombopag)
12.5mg, 25mg, 50mg, 75mg tablets

Blood Products for Life-Threatening Hemorrhage



Blood products are critical to maximizing survival following mass casualty incidents

Blood Products for Life-Threatening Hemorrhage



VELICO MEDICAL
TRANSFORMING TRANSFUSION MEDICINE

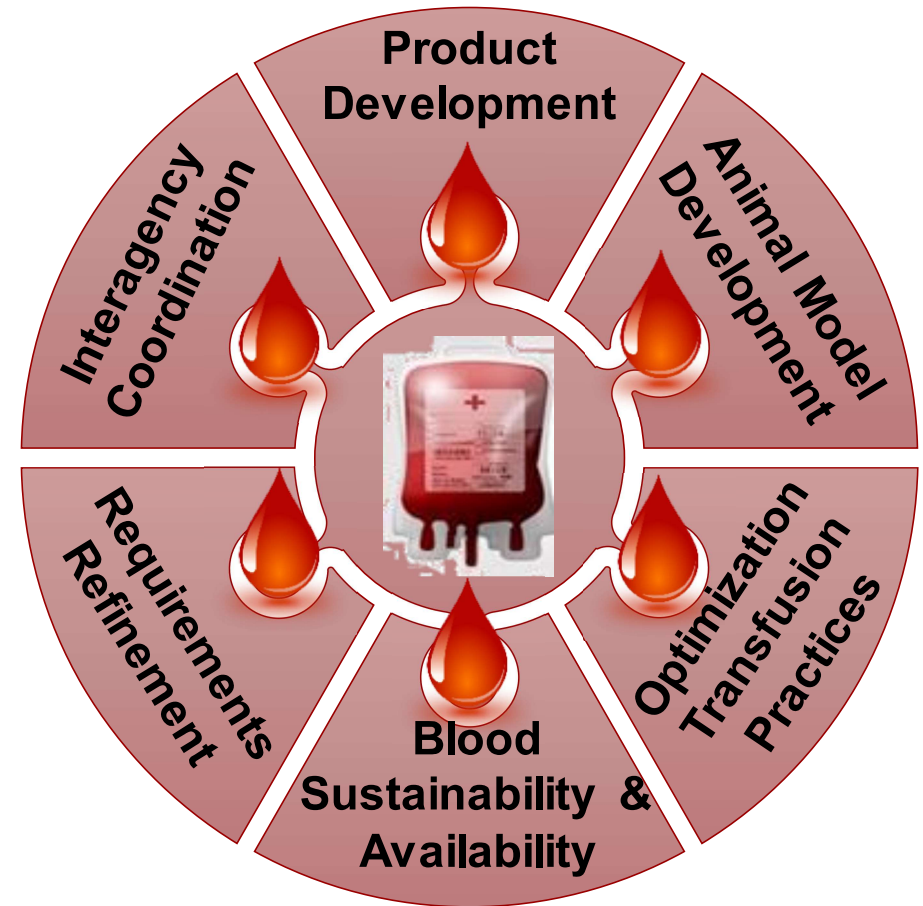


Address blood product gaps and optimize transfusion medicine

Blood Portfolio Activities

Nuggets to chew on

- Prehospital market space
 - Reimbursement
 - Scope of practice
- Sustainability
 - Blood stockpile?
 - Donor recruitment
 - \$\$ donors
 - Nonprofit endeavor...why?
- Manufacturing platforms
- Blood product specifications



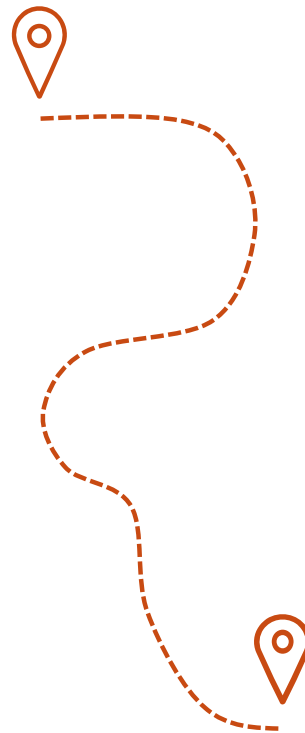
Engage Early and Often

BARDA Tech Watch



- > Radiation/trauma data
- > Commercial indication data
- > Development stage/TRL
- > Regulatory status and strategy
- > Concept of use
- > Business case

[Request a TechWatch Meeting](#)



BARDA BAA

(Broad Agency Announcement)

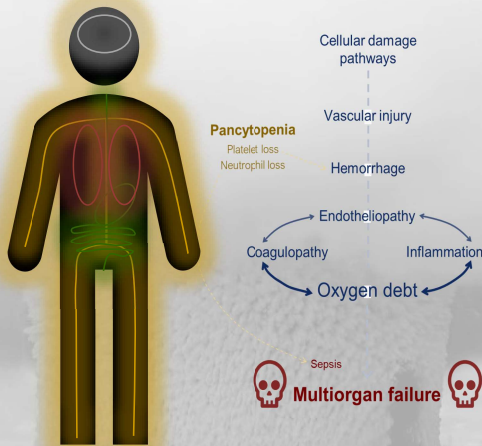
Radiological and Nuclear Medical Countermeasures (Area of Interest #4)

- > Pathophysiology MCM; blood; enabling technologies
- > Radiation injury, trauma, or related indication
- > Technology readiness level (≥ 5)
- > Held pre-IND meeting with US FDA



GOAL

Improve *radiation injury and trauma* health outcomes for all victims of nuclear detonations and radiation exposure



Radiological & Nuclear MCMs Program

FOCUS AREAS & STRATEGIC ACTIONS

- **Hematopoietic:**

- Improve all aspects of hematopoietic injury (radiation and trauma induced) through targeted natural history

- **Innovation:**

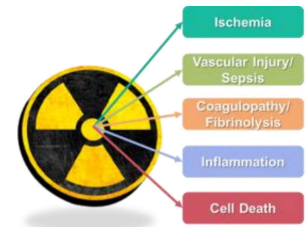
- Blood products – sustainable, robust traditional and next generation blood products
- Enabling technology development (e.g., tissue chips)
- Develop targeted natural histories for unmet areas of pathophysiology (e.g. ischemia, endotheliopathies)
- Employ new technologies and treatment for robust systemic care

- **Repurposing:**

- Leverage commercially available products
- Leverage across threat spaces
- Target underserved and special populations (e.g., pediatrics)

- **Preparedness and Sustainability:**

- Repurpose existing commercial products and enable vendor managed inventories with stock rotation
- Develop new products with relevant commercial capacity in regular health care settings
- Drive creation of new essential market space (e.g., pre-hospital)
- Provide interagency support for disaster response





[medicalcountermeasures.gov](https://www.medicalcountermeasures.gov)
Portal to BARDA: Register to request a TechWatch meeting!



[sam.gov/](https://sam.gov)
Official announcements and info for all government contract solicitations



aspr.hhs.gov/MCM/
Program description, information, news, announcements



drive.hhs.gov
Learn about DRIVE, including our Accelerator Network and EZ BAA



www.usajobs.gov
Join the team!



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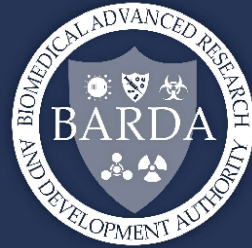
Biomedical Advanced Research and Development Authority



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NOVEMBER 15-16, 2022
VIRTUAL EVENT
WASHINGTON, D.C.



NOVEMBER 15-16

VIRTUAL EVENT

REGISTRATION IS OPEN!!

[BARDA Industry Day 2022: November 15 & 16, 2022 - Virtual Event \(medicalcountermeasures.gov\)](https://www.medicalcountermeasures.gov)

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