



# BURN MEDICAL COUNTERMEASURES CBRN / BARDA

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**October 18-20, 2016**  
**BARDA INDUSTRY DAY**

# Outline

## **BARDA's Burn MCM Development Priorities**

- Primary Goals
- Challenges & Strategy
- Burn MCMs Under Development & Acquisition
- Unmet Needs- Seeking New MCM Candidates

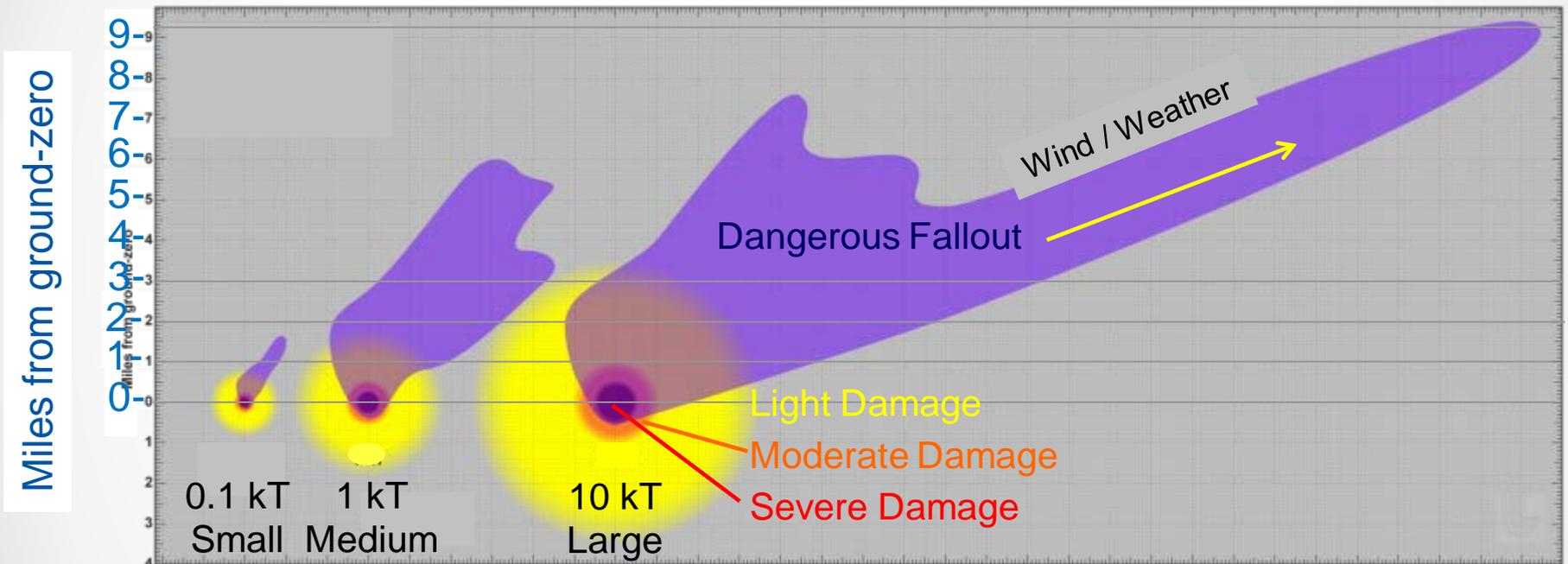
## **Engaging with BARDA**

- At BARDA Industry Day
- Other Portals



# Threat: Improvised Nuclear Device (IND)

- **Severe damage** (collapsed buildings): local
- **Moderate damage** (structural damage): within 1 mile
- **Light damage** (broken windows): within 3 miles
- **Dangerous fallout**: dependent on weather



## Effects:

- **Blast:** overpressure + shockwave → **Trauma**
- **Thermal:** thermal pulse + ignited fires → **Burns**
- **Radiation:** prompt+ fallout → **Acute radiation syndrome, cutaneous radiation injury**



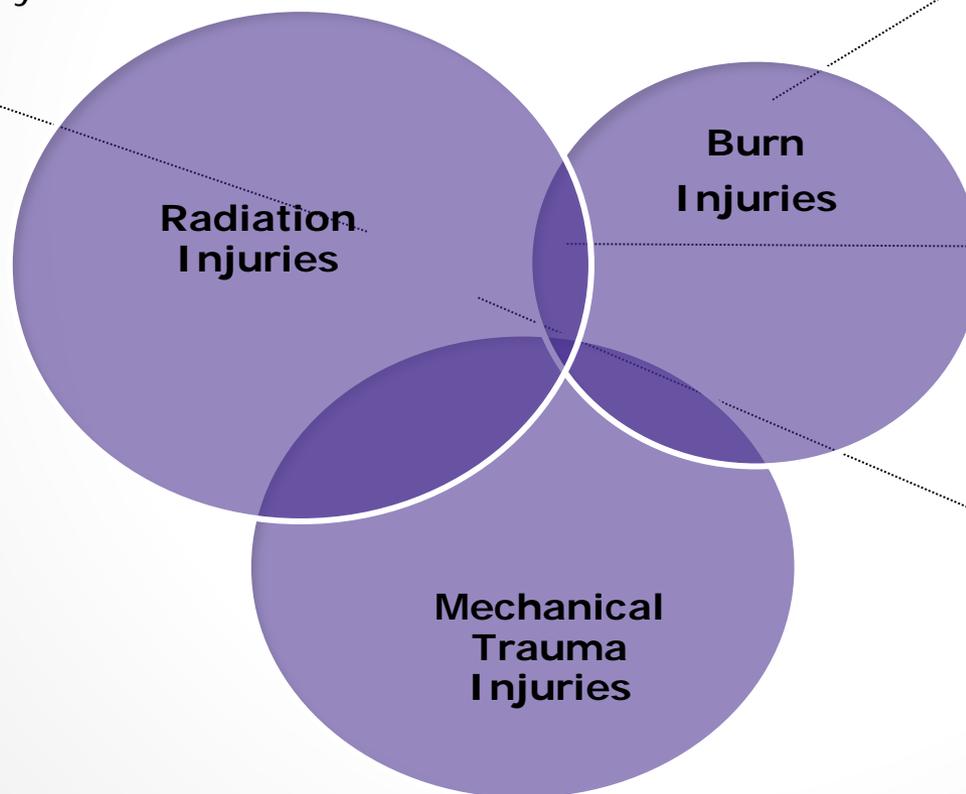
# Medical Consequences: IND Detonation

## Radiation Injuries :

- Acute Radiation Sub-syndromes
  - Hematopoietic: cytopenias
  - Gastrointestinal & Pulmonary Injury
- Decorporation
- Biodosimetry

## Burn Injuries

- Flash Burns
- Secondary Fires

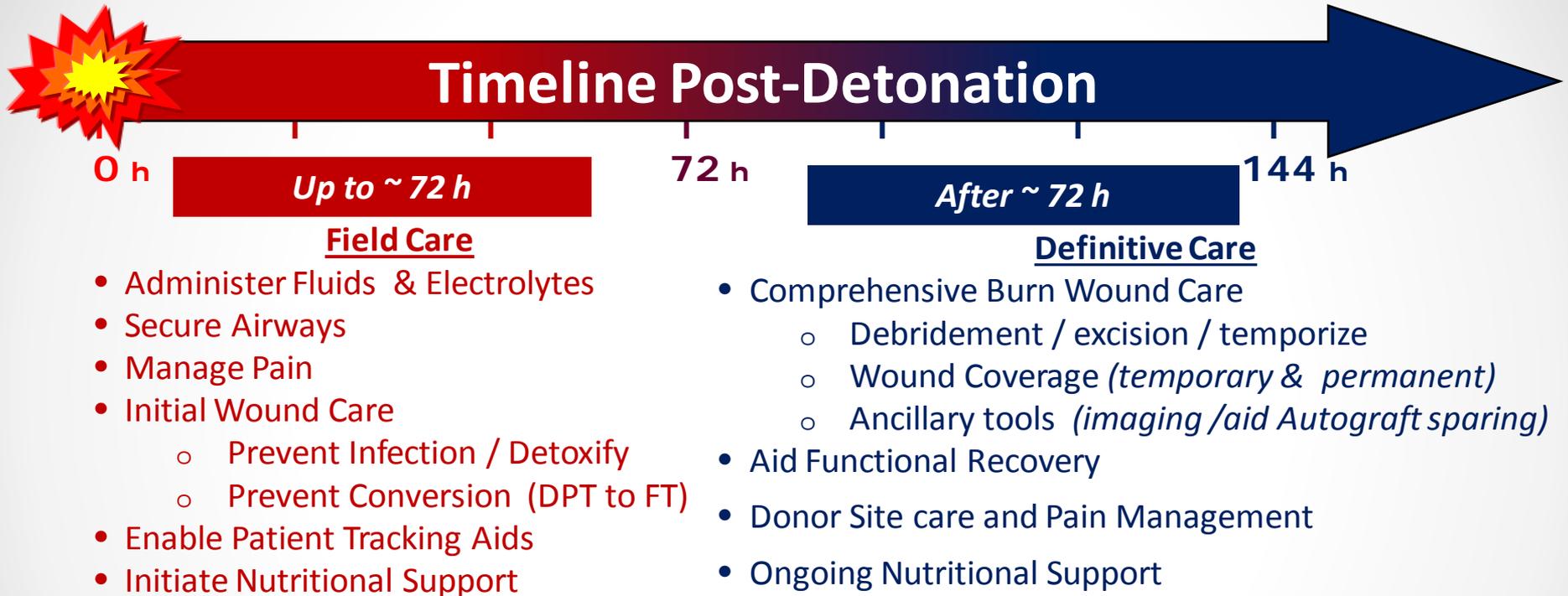


**Concomitant Burn & Radiation injury**

Cutaneous Radiation Injuries (CRI)  
*Exposure to Radioactive fallout & beta-radiation*

Distribution Size is Notional

# Treatment Goals: MCMs for Thermal Burns



# Challenges of Definitive Care (>72 hr to weeks)

- **Burn care is Specialized Care....relatively small market**
  - Estimated 350 burn surgeons in North America
  - <10,000 surgeries a year
- **National burn treatment capacity is limited**
  - 127 burn centers nationwide: ~1800 burn beds total
  - Average daily availability: ~400-200 burn beds
- **Burn care is labor and resource intensive**
  - Requires specific medical expertise - *excision, grafting, etc.*
  - Long hospital stays – *1 to 1.5 day per %TBSA*
  - Higher medical resource utilization - *1 nurse per 1 patient*



# Limitations in US for Definitive Burn Care

## 1. Treatment Capacity

- Burn surgeons & Expertise
- Infrastructure & Communication
- Transfer Policies

## 2. Efficient Throughput (in mass casualty)

- Procedures with '*bottlenecks*'
- Products with ability to 'temporize'
- Need for 'Smart' products



# BARDA's Solution

Addressing Definitive Care (>72 hr to weeks)

## I. Expand Capacity for Definitive Care

- Ease of Use
- Reduce Resource Burden
- Reduce Demand for Autograft

## II. Expand Timeframe / Increase Throughput

- Limit Conversion to FT burns
- Temporizing strategies
- Efficacy even with delayed treatment

- Shorten hospital stay
- Reduce need for surgery
- Reduce patient morbidity
- Leverage trauma surgeons
- Enable smaller autograft or Skin substitutes

**Comprehensive – Adoptable – Sustainable**



# Definitive Care MCM Products Under Development at BARDA

## *Thermal Burn Definitive Care Continuum*

Days

Weeks

Months

Limit Burn Conversion

Adjuncts to Accelerate Healing /  
Aids to Spare Autografts

Temporize Burns

Skin Substitute / Spare Donor  
Site Morbidity & Autograft

Improve Clinical  
Outcome

Aid Debridement/ Excision

**Arteriocyte- PRP-  
BioBandage**

**Avita (ReCell)- Autograft  
Sparing**

**PolyNovo- BTM  
Biodegradable Matrix**

**MediWound- Non-  
Surgical Debridement**

**Cytori- ADRCs Adjunct for STSG**

**Spectral MD- DeepView Imaging  
System**

**Stratatech- Stratagraft Skin  
Substitute**

**Comprehensive – Adoptable – Sustainable**

**PBS \$**

**ARD \$**



# Addressing Treatment Bottlenecks in Skin Graft during Definitive Care

Minimize Surgical Debridement  
Enzymatic @bedside  
(NexoBrid)



Use less Donor Tissue  
Autograft Sparing  
(ReCell)



Avoid need for donor tissue  
Use Skin substitute  
(StrataGraft)



Direct use of Skin substitute  
(StrataGraft)

Accelerate healing with cells  
(ReCell)



# Definitive Care MCM Products Under Procurement

- **Most Advanced Products in the Portfolio**
  - NexoBrid – enzymatic debridement product
  - Recell – autograft-sparing product
  - Stratagraft – cell-based skin substitute
- **Under Vendor-Managed Inventory**
  - Enabled by continuous demand for routine use
  - Products may have market presence for chronic wounds
  - Increased demand = increased feasibility for larger VMIs
- **Geared for Integration into Routine Care**
  - Products would improve patient care
  - Products could lower overall cost of definitive care



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# Definitive Care MCM Products

## Unmet Needs- Seeking New Candidates

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Aid Debridement/ Excision

**1- New Products to Prevent  
or Limit Burn Conversion**

**2- Easy to Use-  
'Smart' Imaging Systems**

**3- New Allogenic / Biologicals or  
small molecules serve as  
adjuncts to Accelerate Healing**



# Definitive Care MCM Products

## Unmet Needs- Seeking New Candidates

### *Thermal Burn Definitive Care Continuum*

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**1- New Products to Prevent**

### **Key Desirable Attributes**

- Topical / Easy to administer even in large TBSA
- Safe on full thickness burns.
- Reduce patient morbidity/ pain.
- Has an MOA rationale that can be substantiated
- Easy to mfr; Off-the-shelf; sustainable in market with other clinical indications for use.



# Definitive Care MCM Products

## Unmet Needs- Seeking New Candidates

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**2- Easy to Use-  
'Smart' Imaging Systems**

### Key Desirable Attributes

- Non-invasive; Easy to use in early triage assessments; Integrate into current care practices (e.g. hand-held, portable / bedside).
- Provide rapid, reliable guidance on burn depth-healing potential & need for surgery (may not be a diagnostic). Sustainable-other clinical uses.
- Aid burn surgeons in multiple stages of burn care (e.g. assessment of viability of wound bed)



# Definitive Care MCM Products

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### Key Desired Attributes

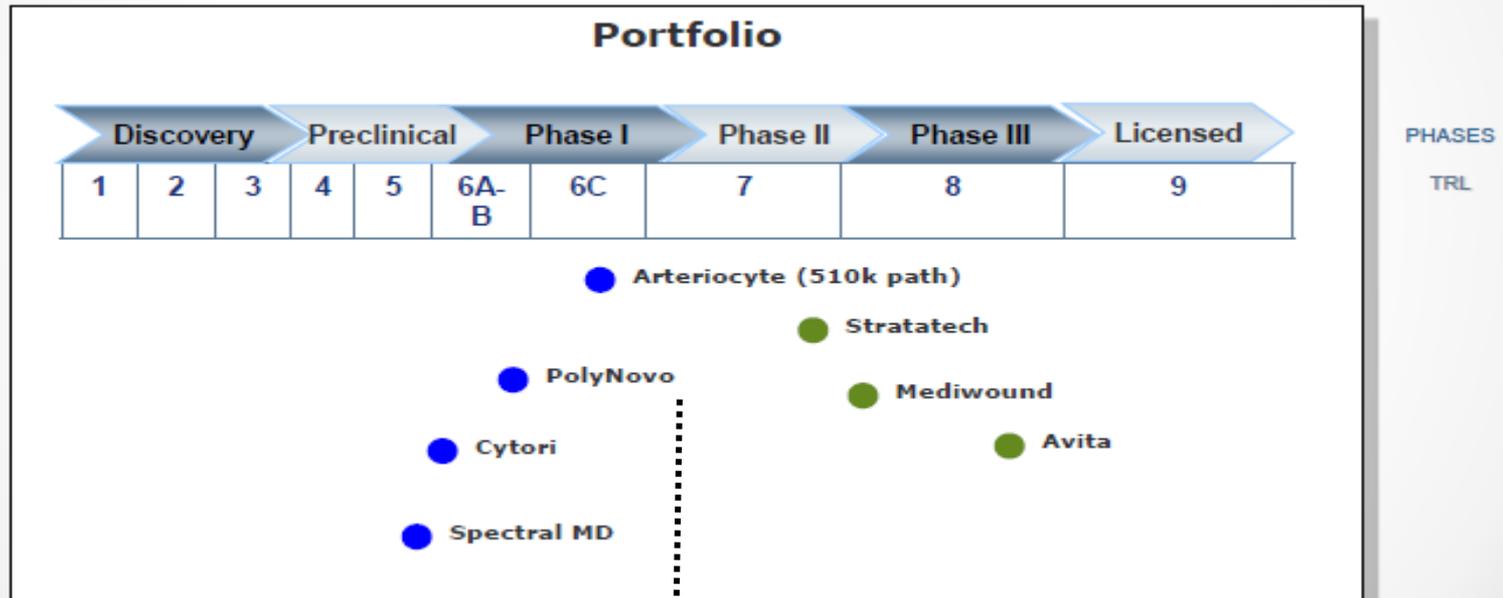
- Easy to integrate in current SOC.
- Safe, off-the-shelf; without the need for additional procedures (e.g. allogenic products).
- Can substantiate rationale for MOA to accelerate healing.
- Commercially sustainable with other indications for use.

**3- New Allogenic / Biologicals or small molecules serve as adjuncts to Accelerate Healing**



# Burn MCM Portfolio Snapshot

**BARDA is building burn care preparedness by solutions which are Comprehensive – Adoptable – Sustainable**



- Meet TRL requirements
- Have a Regulatory Strategy

**Seeking New MCMs to address unmet need in three areas :**

- 1. Limiting Burn Conversion**
- 2. Smart Imaging**
- 3. Adjuncts to Accelerate Healing**



# Engaging BARDA Burn Team

- At Industry Day: Learn more at..
  - Narayan Iyer [[narayan.iyer@hhs.gov](mailto:narayan.iyer@hhs.gov) or 202-510-6609]
  - Julio Barrera-Oro, David Simon; Danielle Turley ; Oxana Selivanova
- Near-Term:
  - Visit [www.medicalcountermeasures.gov](http://www.medicalcountermeasures.gov)
    - Learn more & Register & Request a Meeting (TechWatch)
  - Visit ASPR-TRACIE (Stands for Technical Resources-Assistance Center – Information Exchange)



[ASPRtracie.hhs.gov](http://ASPRtracie.hhs.gov)



1-844-5-TRACIE



[askasprtracie@hhs.gov](mailto:askasprtracie@hhs.gov)



# Partners in Changing Burn Care Paradigm

## Building Burn Care Preparedness

Concerted Effort of Governmental Agencies – Companies - Non-Profits



# Thank You

