



BARDA Thermal Burn Medical Countermeasures Program

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BARDA Industry Day
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Outline

BARDA's Burn Medical Countermeasures (MCMs) Development Priorities

- Primary Goals
- Challenges & Strategy
- Burn MCMs Under Development & Acquisition
- Unmet Needs- Highlighting New Priorities

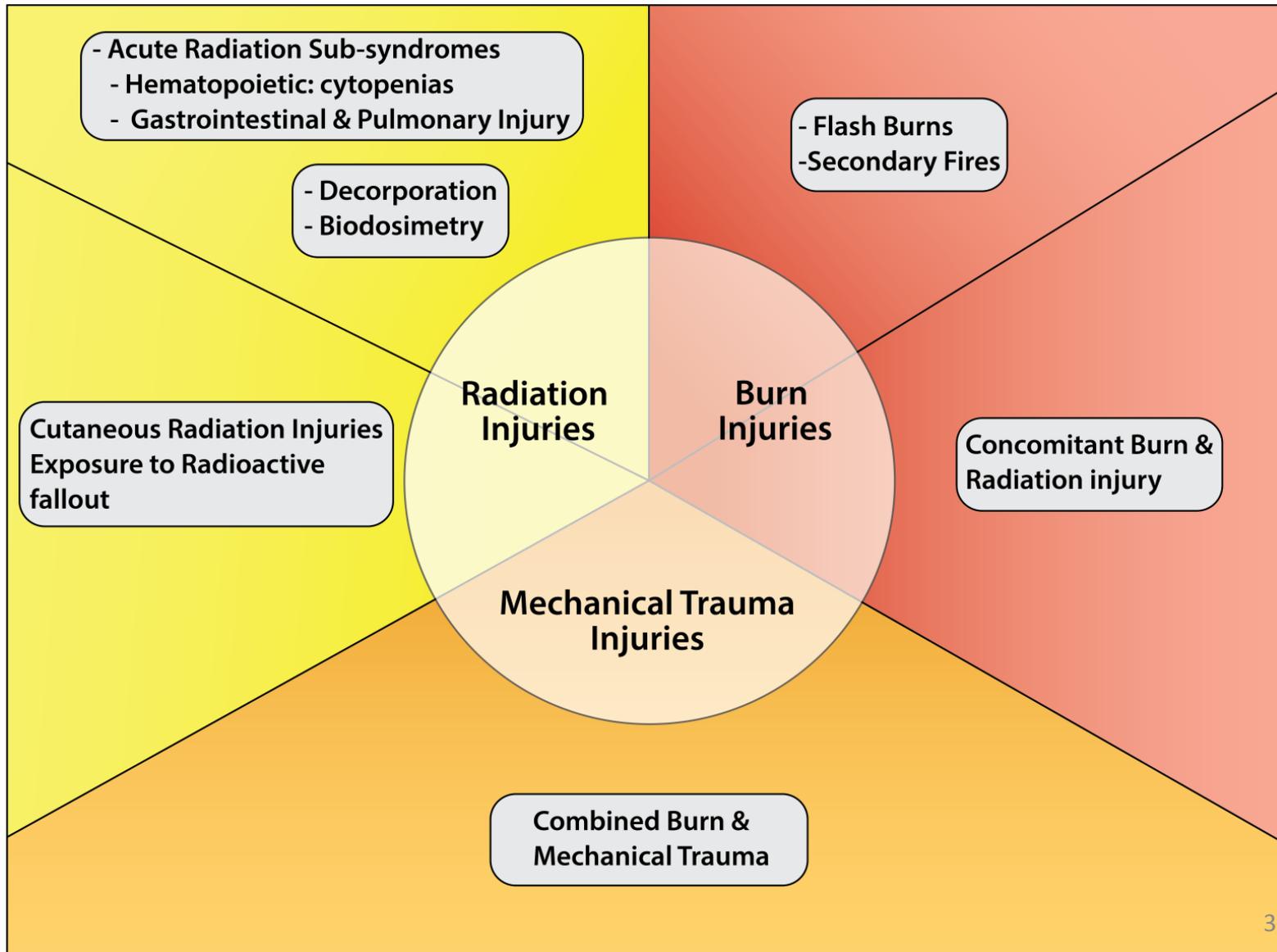
Engaging with BARDA

- At BARDA Industry Day
- Other opportunities





Medical Consequences: Improvised Nuclear Device (IND) Detonation





Treatment Goals: MCMs for Thermal Burns



- 0 h** **Up to ~ 72 h**
- Field Care**
- Administer Fluids & Electrolytes
 - Secure Airways
 - Manage Pain
 - Initial Wound Care
 - Prevent Infection / Detoxify
 - Prevent Conversion (deep partial to full thickness)
 - Enable Patient Tracking Aids
 - Initiate Nutritional Support

Addressed via
Burn Blast Kit MCMs in the
Strategy National Stockpile

- 72 h** **After ~ 72 h** **144 h**
- Definitive Care**
- Comprehensive Burn Wound Care
 - Debridement / excision / temporize
 - Wound Coverage (*temporary & permanent*)
 - Ancillary tools (*imaging /aid Autograft sparing*)
 - Aid Functional Recovery
 - Donor Site care and Pain Management
 - Ongoing Nutritional Support

Addressed via
Broad Agency Announcement (BAA)
and Project BioShield (PBS) Awards

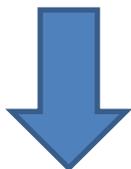




Addressing Field Care: MCMs to control infection

Silverlon™ by Argentum Medical

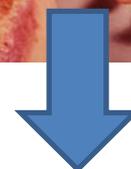
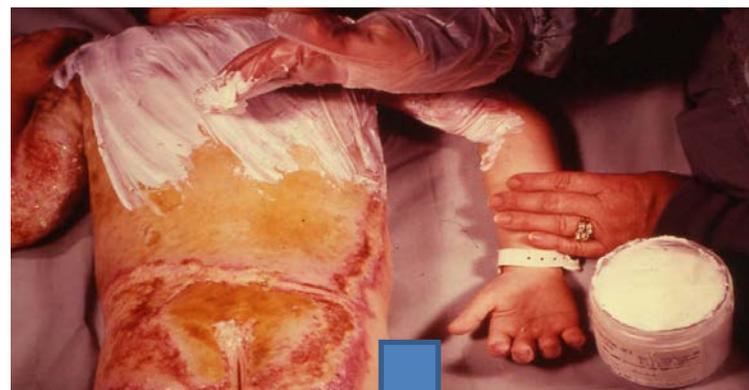
Interagency Agreement with Defense Logistics Agency



Previous Approach

Silvadene Cream

- Painful
- Need to sedate patients
- Need for multiple/daily applications



2015 BARDA Acquisition to the
Strategy National Stockpile

Current Approach

Silverlon - Burn Dressing

- Easy to use
- Applied once for up to 7 days
- Field tested by warfighters
- Multiple threat potential





Realities of U.S. Definitive Burn Care

72hr



weeks/months

Burn care is Specialized Care....relatively small market

Estimated  burn surgeons in North America



Our nation's burn treatment capacity is limited



- Requires specific medical expertise excision, grafting, etc

- Long hospital stays
1 to 1.5 days per % Total Body Surface Area (TBSA)

- Higher medical resource utilization



1 nurse per 1 patient

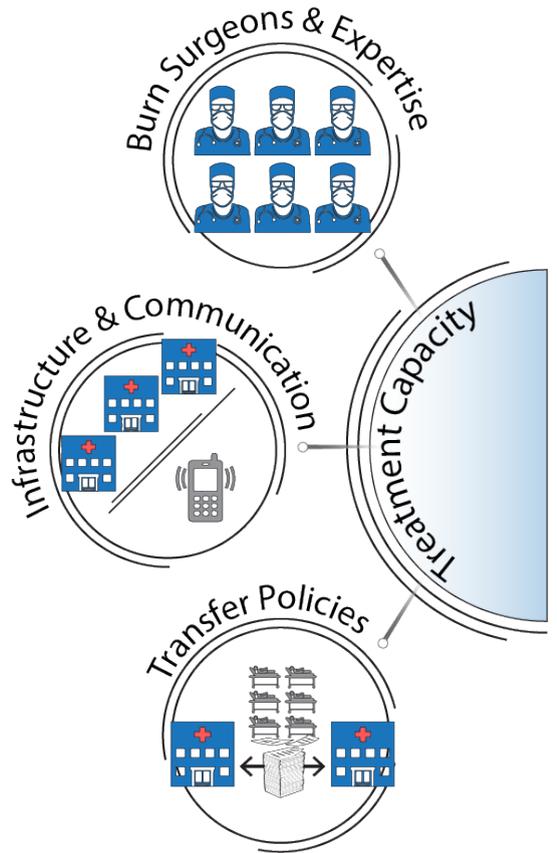
Burn care is labor and resource intensive



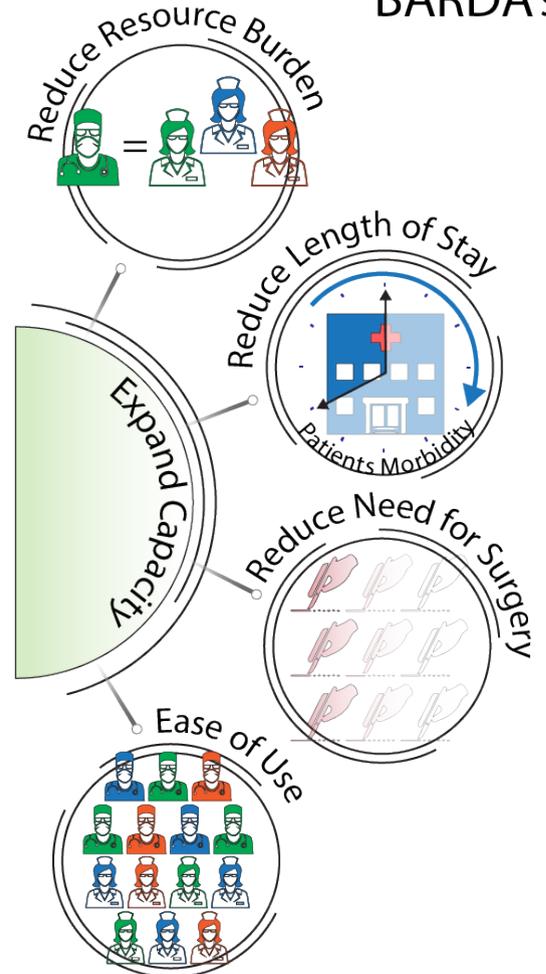


Solutions: Definitive Care

Limitations and Challenges in US



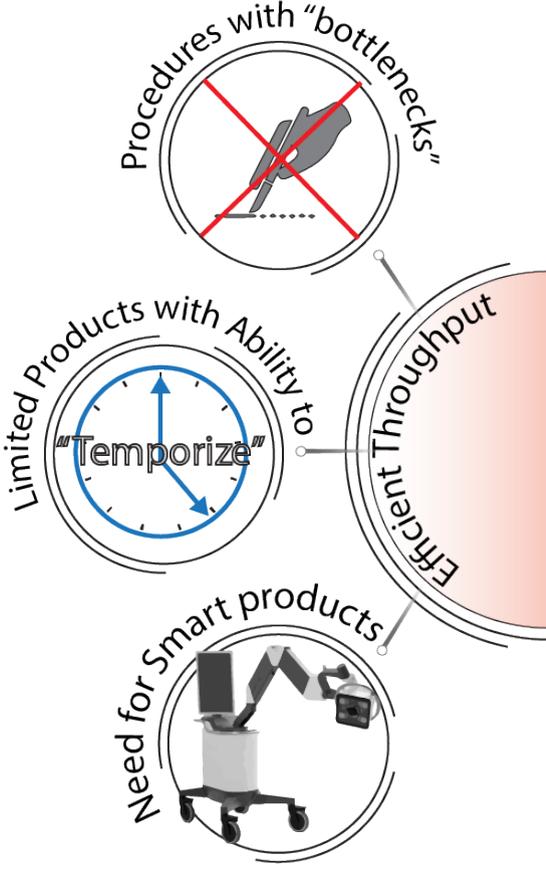
BARDA's Solution



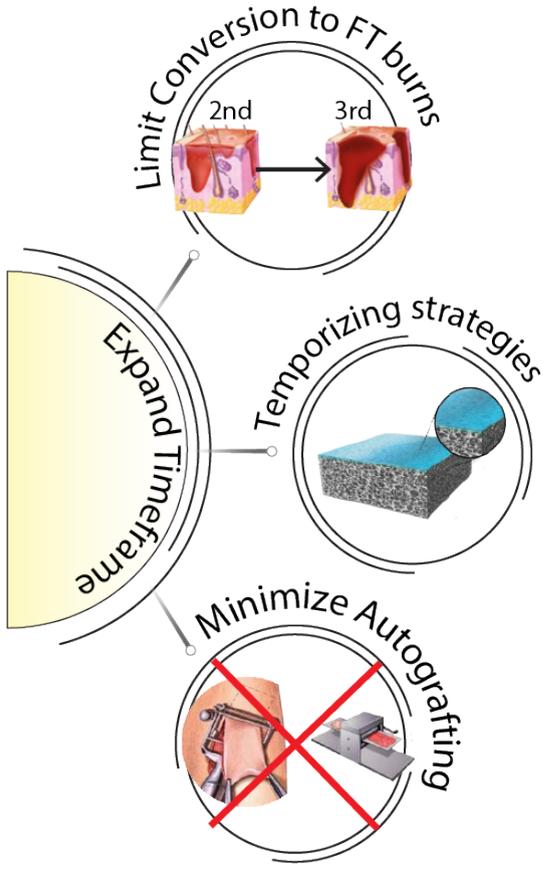


Solutions: Definitive Care

Limitations and Challenges in US

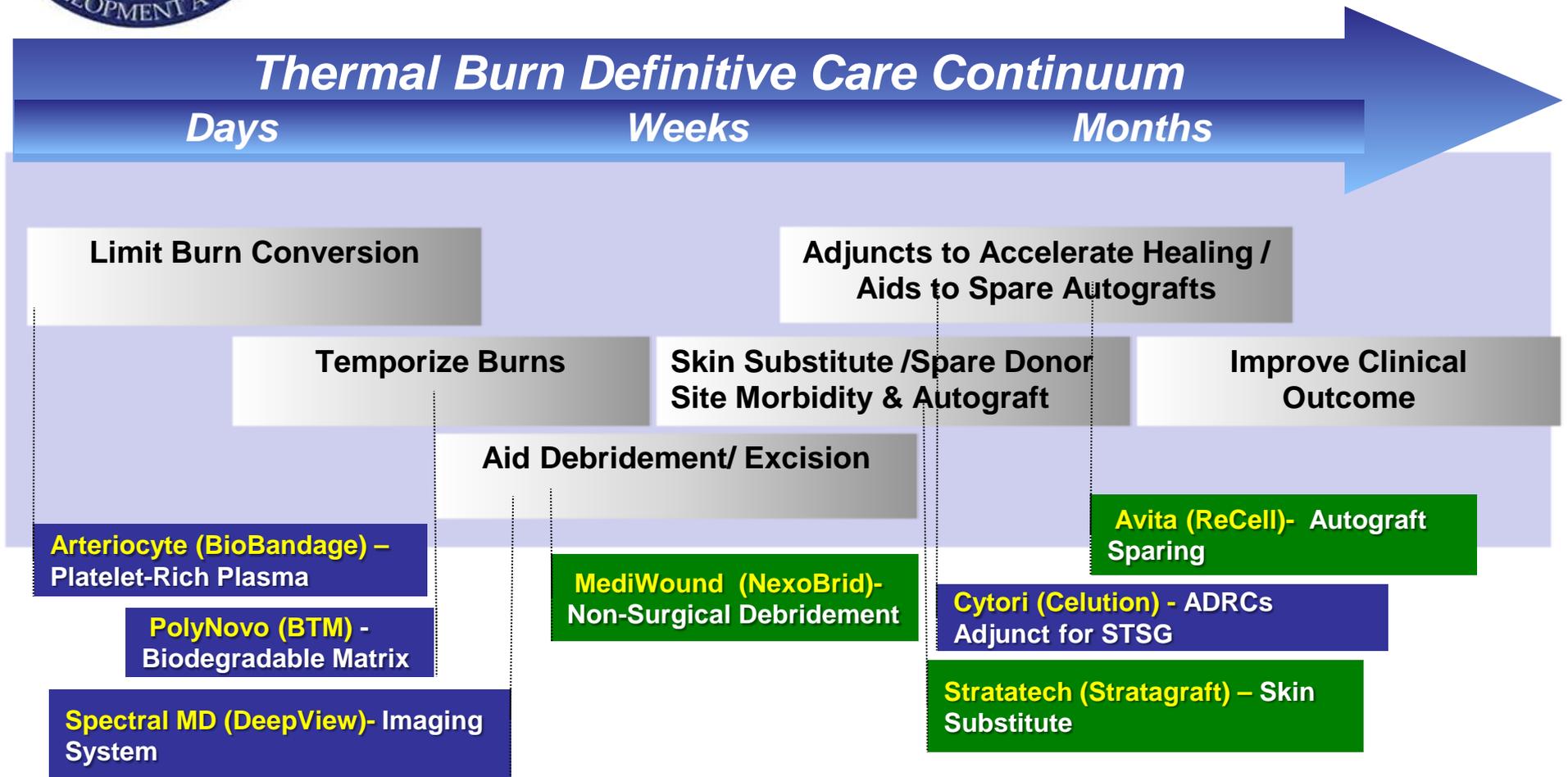


BARDA's Solution





Definitive Care Products Under Development at BARDA



Project BioShield

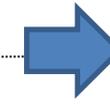
Advanced Research and Development



Increasing Preparedness by Improving Burn Care

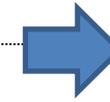
NEXOBRID™

Minimize Surgical Debridement – Enzymatic @bedside



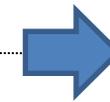
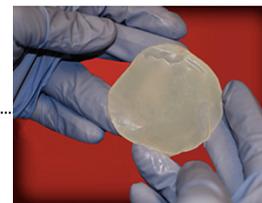
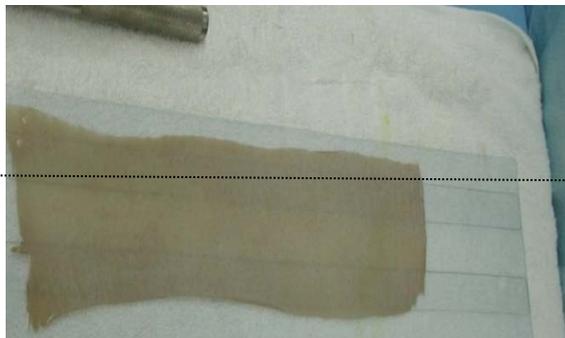
RECELL®

Use less Donor Tissue – Autograft Sparing



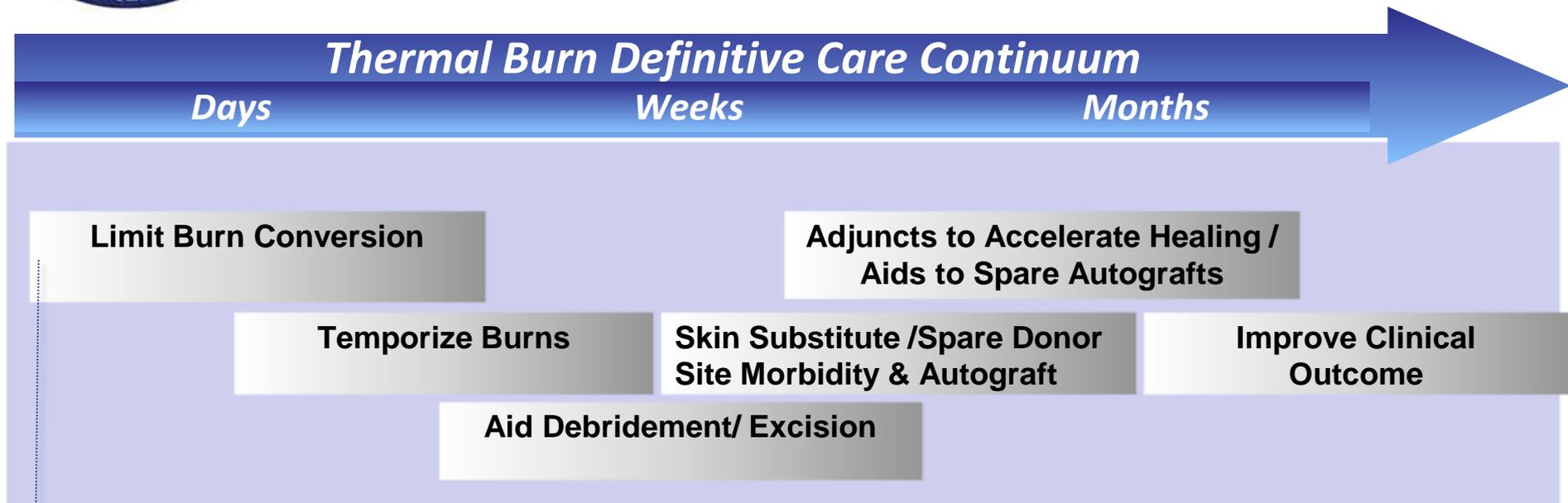
STRATAGRAFT®

Avoid need for donor tissue – Use Skin substitute





Definitive Care Products: Unmet Needs – New Priorities



1- Allogenic Products or Small Molecules to Prevent or Limit Burn Conversion

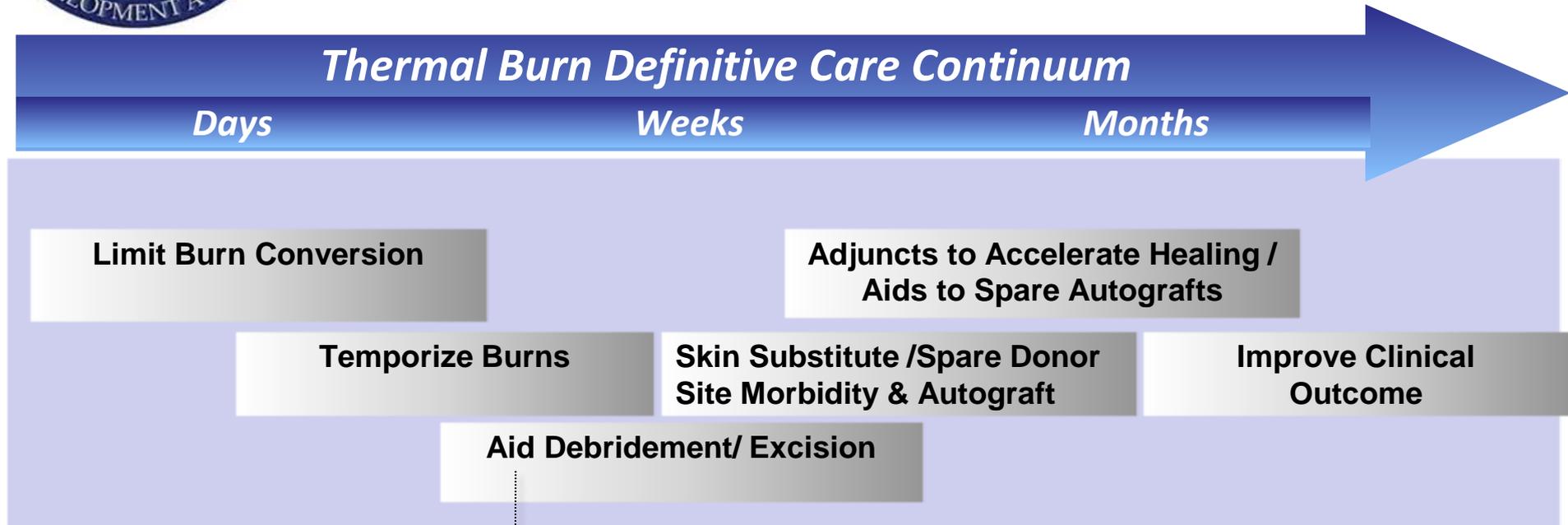
Key Desirable Attributes

- Proof-of-Concept studies showing prevention of burn progression to full-thickness injury
- Topical / Easy to administer even in large area burns
- Safe on full thickness burns.
- Reduce patient morbidity/ pain.
- Has a mechanism of action rationale that can be substantiated
- Easy to produce; Off-the-shelf; (e.g. non-autologous)
- Sustainable in market with other clinical indications (wounds)





Definitive Care Products: Unmet Needs – New Priorities



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

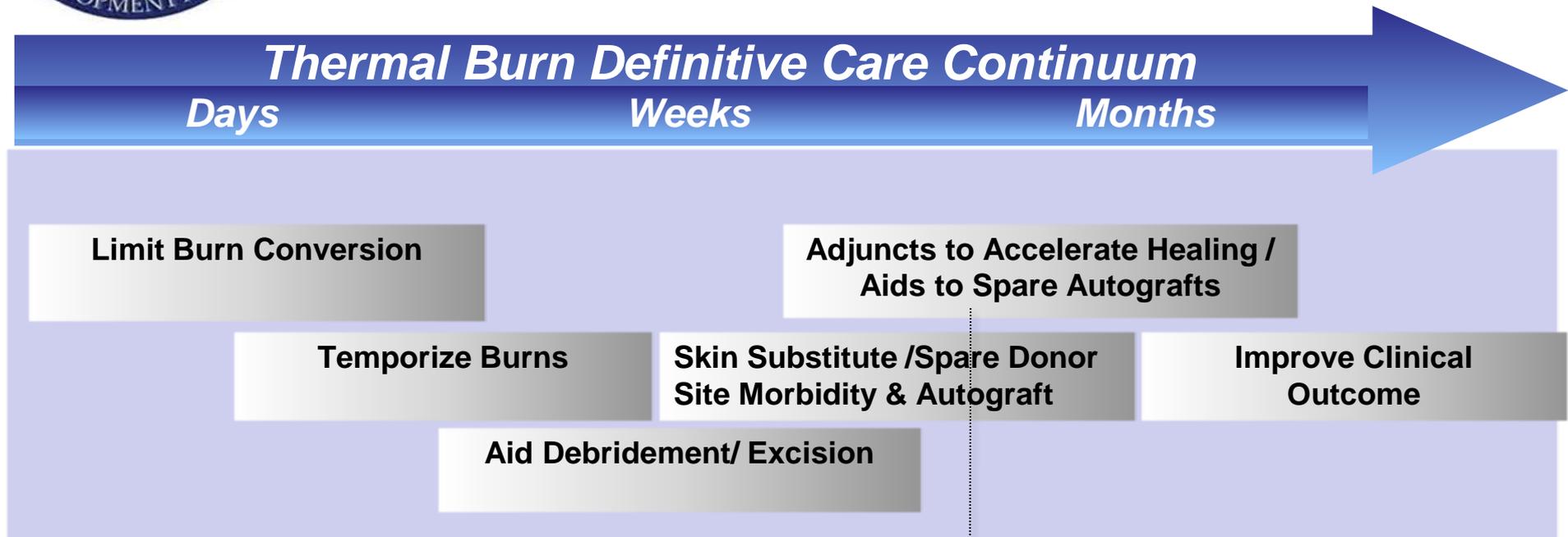
Key Desirable Attributes

- 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).
- Multiplex capabilities to assess wound trauma





Definitive Care Products: Unmet Needs – New Priorities



Key Desired Attributes

- Can substantiate rationale for mechanism of action to accelerate wound closure.
- Easy to integrate in current standard of care
- Safe, off-the-shelf; without the need for additional procedures (e.g. allogenic products).
- Commercially sustainable with other indications for use (wounds).

**3- New products to serve as
adjuncts to Accelerate
Healing**





Additional Unmet Needs: Key Desirable Attributes

4. Products for treatment of inhalational injuries

- Preliminary efficacy data
- Can demonstrate rationale for mechanism of action to lower morbidity
- Open to various product types (imaging, precision ventilation, etc.)

5. Countermeasures for Cutaneous Radiation Injuries (CRI)

- Novel products with preliminary efficacy data in related human clinical condition (e.g. radiation dermatitis)
- Data demonstrating lowered morbidity, prevention of wound progression, or acceleration of resolution

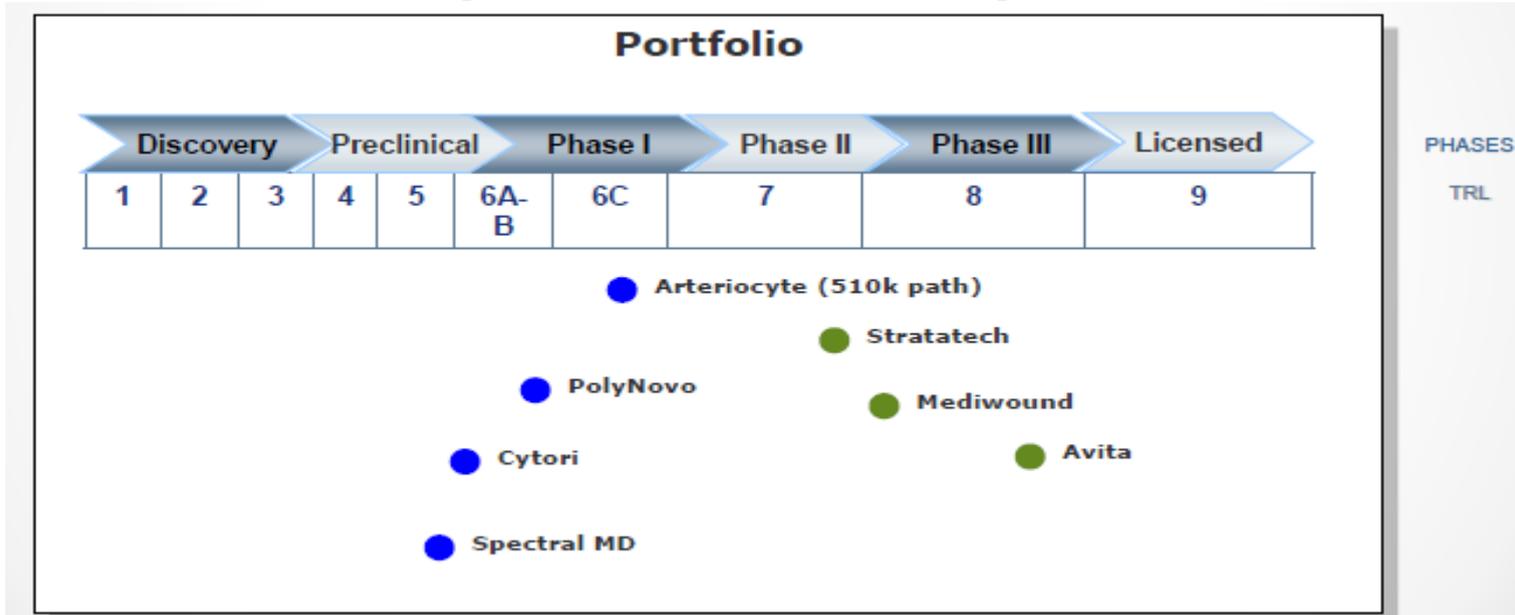
Potential to treat CRI Grades I,II,III





Burn MCM Portfolio Snapshot

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



- Meet Technical Level Readiness Requirements
- Have a Regulatory Strategy to FDA approval

Seeking New MCMs to address unmet need areas :

1. Limiting Burn Conversion
2. Smart Imaging
3. Adjuncts to Accelerate Healing
4. Products for Treatment of Inhalation Injuries
5. Countermeasures for CRI





Partners in Changing Burn Care: Building Preparedness

Concerted Effort of Governmental Agencies – Companies - Non-Profits





Engaging the BARDA Team

- **At Industry Day: Learn more at..**
 - Email: Narayan Iyer [narayan.iyer@hhs.gov]
 - Call: Julio Barrera-Oro [202-260-0393]
 - Reach Out: David Simon; Danielle Turley ; Oxana Selivanova; Janelle Hurwitz





Online Resources

<https://www.medicalcountermeasures.gov/home.aspx>

- Portal to BARDA: Register to request a **TechWatch** meeting

<https://www.fbo.gov/> (“FedBizOpps”)

- Official announcements and info for all government contract solicitations

<https://www.usajobs.gov/>

- Join the team!

<https://www.phe.gov/about/BARDA/Pages/default.aspx>

- Program description, information, news, announcements





THANK YOU

