



# MEDICAL BIOMEDICAL BIODEFENSE

*Symposium*

Support to America's Warfighters and Veterans

September 24-25, 2025

Chapel Hill, North Carolina

**Hosted by:**

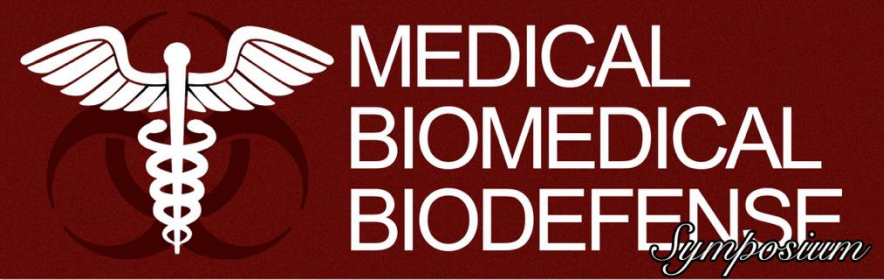
Office of United States Senator Thom Tillis

Office of United States Senator Ted Budd

North Carolina Military Business Center

North Carolina Biotechnology Center

Medical Technology Enterprise Consortium



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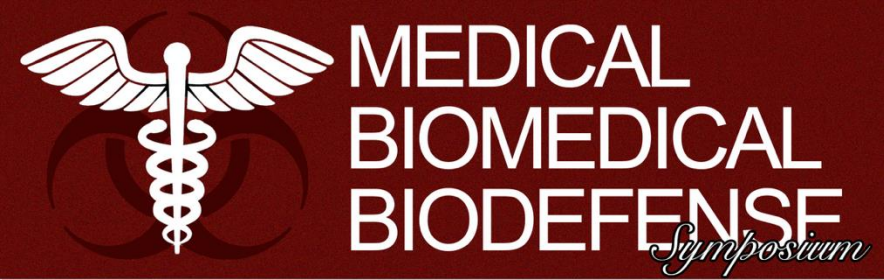
# Welcome Remarks



**Scott Dorney**

Executive Director

North Carolina Military Business Center



Support to America's Warfighters and Veterans  
September 24-25, 2025  
Chapel Hill, North Carolina

# Thank You Sponsors!

## Silver Sponsors



**North Carolina  
Biotechnology Center®**

## Reception Sponsor



## Bronze Sponsors

Altrazeal Life Sciences Inc.  
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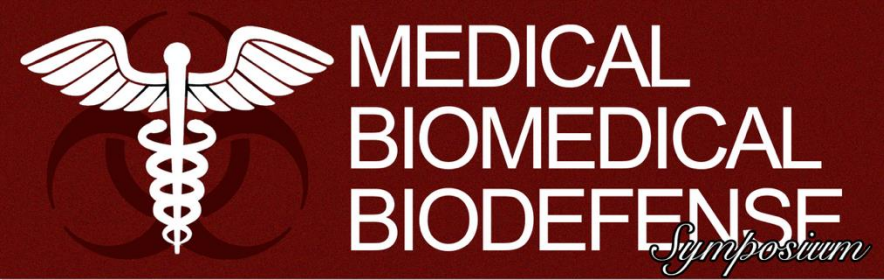
## Gold Sponsors



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## Small Business Sponsors

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# Reception Sponsor Remarks



Clinical Research  
STRATEGIES

Built to Think, Evolve & Endure.

**Julie Cramer**  
Senior Director of Clinical  
and Regulatory Affairs  
Clinical Research Strategies

# CRS IS A PROUD ATTENDEE & CO-SPONSOR OF THE 2025 Medical, Biomedical & Biodefense: Support to the Warfighter Symposium

**VISIT THE CRS TEAM  
AT BOOTH 4!**



**Clinical Research  
STRATEGIES**

Built to Think, Evolve & Endure.



# Boutique Executive Consulting Group & Clinical CRO

- Founded on 65+ combined years of veteran experience in *regulatory strategy and submissions, clinical operations, risk management, manufacturing, and continuous quality improvement* for Top 10 Healthcare Companies, small start-ups, multiple CROs, and military/defense-backed aerospace and optics programs
- Team experience in *integrative project planning & execution* for *first-in-class* technologies associated with:
  - Supporting **DoD, DARPA, NIH, and SBIR** funded research
  - Spoke member of **ARPA-H**
  - Member of **MTEC**
  - Mentors for **M2D2, LifeX, CNY Biotech Accelerator, Alpha Health Labs**

## Conference Representatives



Julie Cramer, PhD



Alyssa Harris, MS



Haley Fuller, PhD



Sidney Lane, PhD

# Emphasis on Clinical, Regulatory, and Quality Pillars

## Clinical

- Clinical strategy, support, authorship, and leadership
- Experience with designing First-in-Man, Proof-of-concept (POC) studies through evaluating Post-Market lifetime studies
- Expertise in:
  - First-in-Man (FIM)
  - Validation Studies
  - Human Factors
  - Post-market / Real World Evidence (RWE)

## Regulatory

- Regulatory strategy, authorship, liaison, and management
- Regulatory pathway assessments (RPA) to prepare / substantiate submissions
- Submissions to/for IRB, US FDA, EC for CE Mark under EU MDR
- Drugs, NSR / SR Devices, Combination products
- 513g, 510k, De Novo, Class I, Q-Sub, BDD, Pre-IDE/HDE or Pre-IND/IND, Pre-RFD/RFD, PMA US FDA pathways

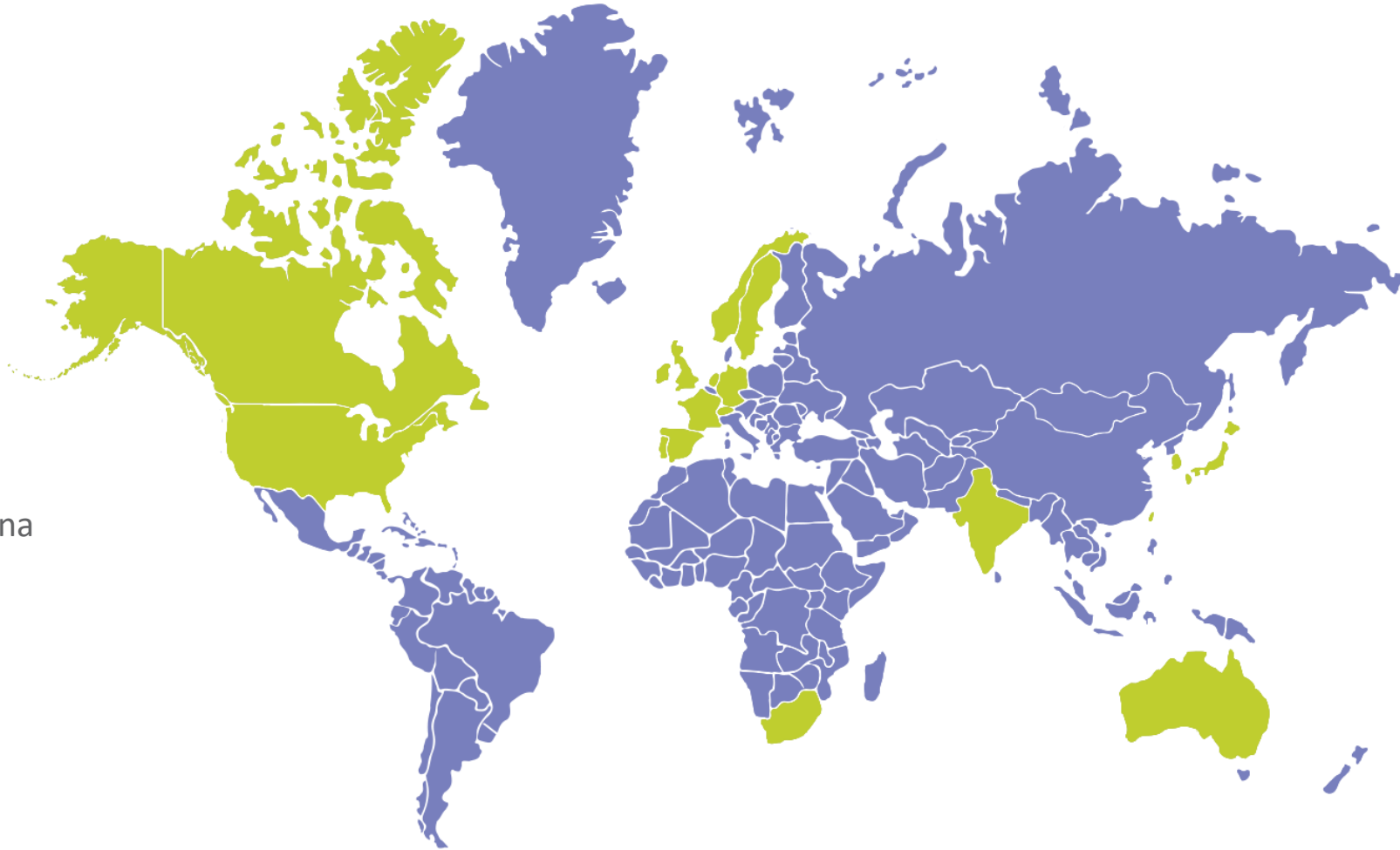
## Quality Assurance

- QMS – 21 CFR 820/ISO13485
- Product Requirements Documents (PRD)
- Risk Management Files (RMF)
- Biocompatibility / sterility testing requirements & reports
- Development of First Article
- Conduct and validate audits



## Serving Global Clients

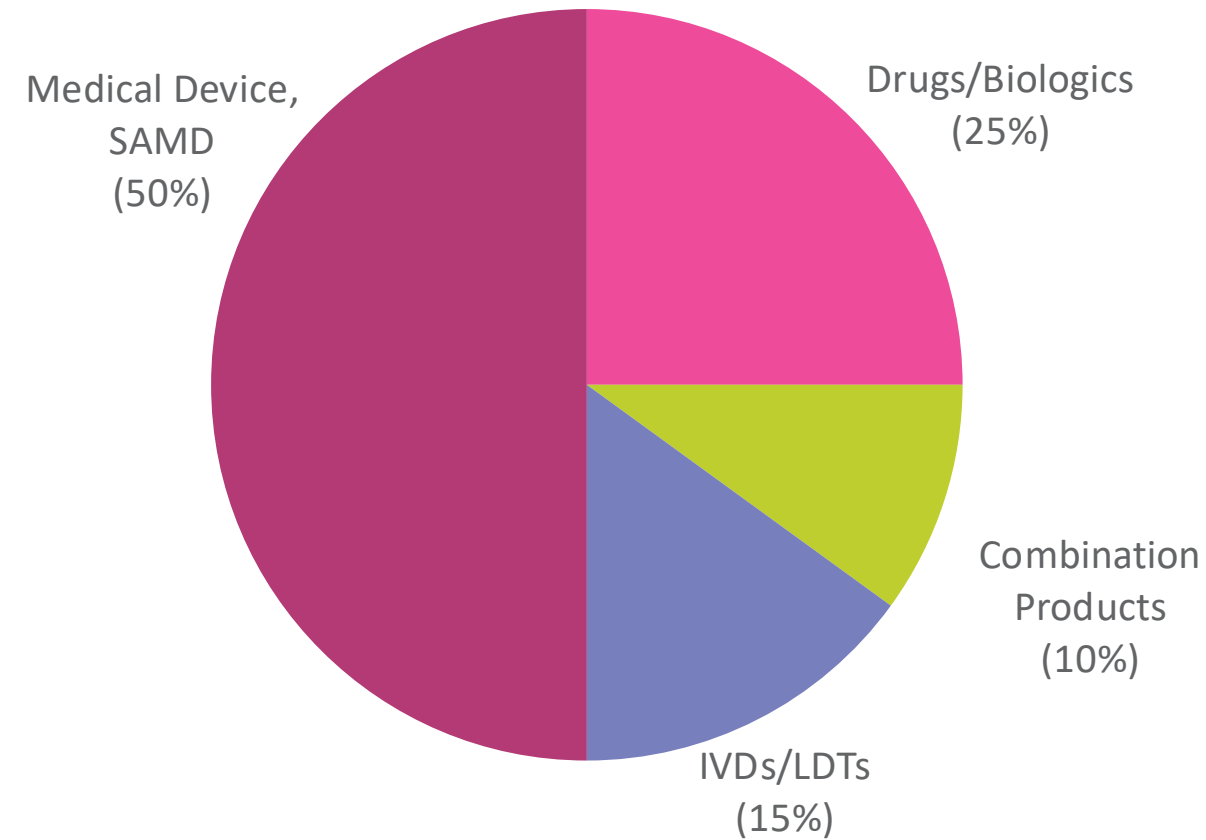
- Austin
- Boston
- Chicago
- Houston
- Minneapolis
- New Jersey
- New York City
- Philadelphia
- Pittsburgh
- RTP, North Carolina
- San Antonio
- Tucson
- Washington, D.C.
- Canada



- France
  - Germany
  - Norway
  - Portugal
  - Spain
  - Sweden
  - Switzerland
  - The Netherlands
  - United Kingdom
- 
- India
  - Japan
  - South Korea
  - Taiwan
- 
- South Africa
  - Australia

# Modalities and Therapeutic Areas Serviced

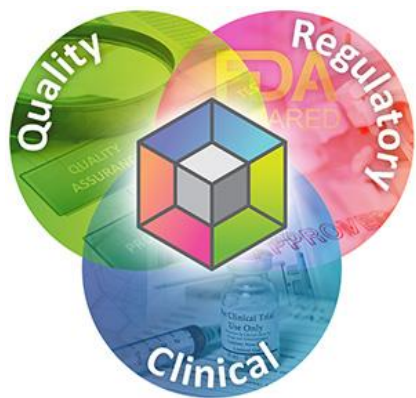
## MODALITIES



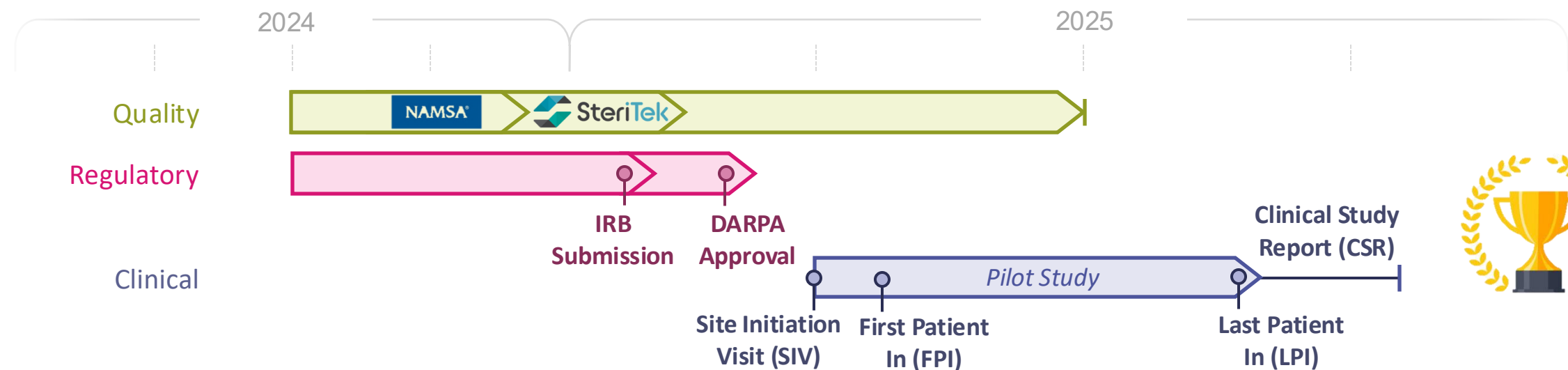
## THERAPEUTIC AREAS

- Aging
- Antibody Therapeutics
- Biosensors
- Cannabis
- Cardiovascular Disease
- Central Nervous System
- Critical Care Medicine
- Dental and Oral Health
- Digital Health
- Gastroenterology
- Genetics
- Immunology
- Infectious Disease
- Men's Health
- Metabolic Disorders
- Microbiome
- Neonates & Pediatrics
- Nephrology & Renal Diseases
- Neurology
- Oncology
- Ophthalmology
- Opioid Abuse
- Orthopedics
- Pain
- Precision Medicine
- Psychiatry & Mental Health
- Rare Diseases
- Radiology
- Regenerative Medicine
- Respiratory Diseases
- Sleep
- Women's Health
- Wound-Healing

# Case Study: DARPA Wound Characterization FIH Study



Client	DARPA and McGowan Institute for Regenerative Medicine		
Objectives	<b>Clinical</b> Initiate & conduct FIH pilot study	<b>Regulatory</b> Support non-significant risk (NSR) submission to IRB	<b>Quality</b> Build & operate Phase I QMS for trial readiness
Barriers	<ul style="list-style-type: none"><li>Academic groups unfamiliar with industry-standard operating procedures</li><li>Incredibly tight timeline</li></ul>		
Results	<ul style="list-style-type: none"><li>IRB and DoD Office of Human Research Oversight (OHRO) approval as NSR device</li><li><b>5 of 5 participants completed; device functionality confirmed in humans and no serious adverse events reported</b></li></ul>		



# Contact



COMPLIANCE,  
GOVERNANCE &  
DUE DILIGENCE



CRO & SPONSOR  
STAFFING



CLINICAL &  
REGULATORY  
AFFAIRS



RISK  
MANAGEMENT &  
QUALITY  
ASSURANCE



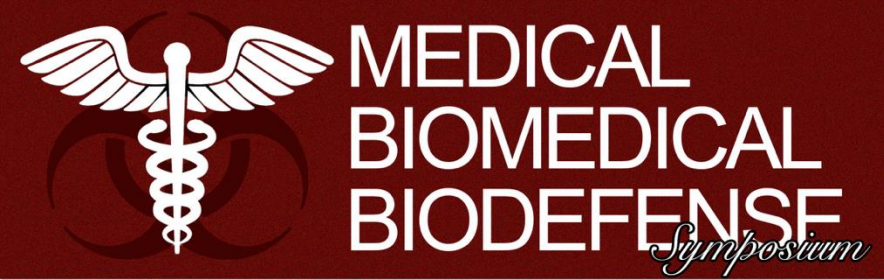
POLICY &  
INNOVATION

## Main Office

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<https://www.linkedin.com/company/clinical-research-strategies>



**VISIT US AT BOOTH #4**



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# Morning Keynote Remarks



**Dr. Carrie M. Quinn**

Deputy to the Commanding General  
US Army Medical Research and  
Development Command

# DHA RESEARCH & DEVELOPMENT AND ARMY MEDICAL MODERNIZATION

## SUPPORTING WARFIGHTER READINESS AND LETHALITY

### MISSION-CRITICAL, THREAT INFORMED AND ADVERSARY-FOCUSED CAPABILITIES



DoD Chemical  
Threat Detection



DoD's Biocontainment  
(BSL2/3/4) Lab with  
Biodefense mission



DoD EA: Medical  
Research, Mitigation,  
and Treatment of Blast  
Injuries



Burn Flight  
Team (BFT)



Centralized DoD  
Diagnostic Labs



PM Soldier  
Medical Devices

#### USNORTHCOM

#### USEUCOM & USCENTCOM

#### USINDOPACOM

**STRATEGICALLY  
LOCATED TO  
SUPPORT THE  
COMBATANT  
COMMANDS**

• HOMELAND BIODEFENSE  
• REACHBACK STRATEGIC SUPPORT

• AMR SURVEILLANCE  
• VECTOR SURVEILLANCE  
• GCC EXERCISE SUPPORT

### SUPPORTING NATIONAL SECURITY THROUGH GLOBAL PRESENCE

- ★ FORWARD DIRECTORATES
- ★ ENDURING PRESENCE
- RDT&E
- SURVEILLANCE

#### 4,800 WORKFORCE

MILITARY • CIVILIANS  
• CONTRACTORS

#### SPECIALIZING IN

SCIENCE • GLOBAL HEALTH ENGAGEMENT •  
BIOMEDICAL INTELLIGENCE • TECHNOLOGY  
DEVELOPMENT • BIOMEDICAL SURVEILLANCE •  
• PROGRAM MANAGEMENT • EMERGING AND  
ADVANCED TECHNOLOGIES • MISSION COMMAND

#### USSOUTHCOM

#### USAFRICOM

### EXECUTES \$650M OF CONGRESSIONAL SPECIAL INTEREST FUNDS

THROUGH CONGRESSIONALLY  
DIRECTED MEDICAL  
RESEARCH PROGRAMS  
(CDMRP)

• DISEASE SURVEILLANCE  
• PEPFAR  
• GLOBAL HEALTH DIPLOMACY  
• GCC EXERCISE SUPPORT

• BIO-SURVEILLANCE RESEARCH  
• FORCE HEALTH PROTECTION  
• OPERATION PATHWAYS  
• GCC EXERCISE SUPPORT

## STRATEGIC LINES OF EFFORT INTEGRATING MEDICAL R&D TO WARFIGHTER REQUIREMENTS

### SURVIVABILITY AND LETHALITY

We are dedicated to revolutionizing military medicine by developing cutting-edge trauma care solutions, deployable advanced treatments, and life-saving medical technologies. By harnessing the power of artificial intelligence, telemedicine, and human performance optimization, we empower our forces to remain resilient, adaptable, and unmatched in lethality across any operational scenario.

### MEDICAL MODERNIZATION

The rapid evolution of combat systems and battlefield tactics demands equally advanced medical innovations to ensure our soldiers can survive, recover, and remain mission-ready. From establishing blast exposure thresholds to developing durable blood products for austere environments, medical modernization enhances survivability and strengthens the operational effectiveness of our forces.

### PROTECTION AND READINESS

By advancing technologies that optimize physical and cognitive performance—boosting endurance, decision-making, and operational effectiveness—we ensure our forces are equipped to meet any challenge. At the same time, we develop medical solutions to protect against chemical and biological threats, maintaining readiness in contaminated environments. A protected force is a ready and resilient force.

### DETERRENCE AND POSTURE

We strengthen deterrence and posture by ensuring our forces are ready, agile, and strategically positioned to respond to emerging threats. By aligning our efforts with Combatant Command priorities, we address operational health challenges, strengthen partnerships, and enhance global mission execution, ensuring the force remains prepared to deter adversaries, protect national interests, and sustain global stability.

**PROTECT the warfighter • PROJECT the threats • SUSTAIN the fighting force**