



U.S. Army Medical Research and Materiel Command (USAMRMC)

Science and Technology Overview

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1. Drivers and Scope of USAMRMC S&T
2. USAMRMC Research Programs
3. USAMRMC Laboratories
4. Working with USAMRMC



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Drivers: Health & Performance Threats



USAMRMC Responds to Threats to Service Member Health and Performance



Endemic Disease Threats

- ▶ Parasitic Diseases
- ▶ Bacterial Diseases
- ▶ Viral Diseases

Chemical/Biological Warfare Threats

- ▶ Bacterial Threats
- ▶ Viral Threats
- ▶ Toxin Threats
- ▶ Nerve Agents
- ▶ Vesicant Agents
- ▶ Blood Agents

Simulation Training

- ▶ Basic Training
- ▶ Specialty Training
- ▶ Competency Training

Environmental Hazards

- ▶ Heat and Cold
- ▶ Altitude
- ▶ Toxic Industrial Chemicals & Materials

Battle Sequelae

- ▶ Loss of limbs
- ▶ Loss of tissue
- ▶ Loss of vision
- ▶ Pain

Combat Injuries

- ▶ Hemorrhage
- ▶ Head Trauma
- ▶ Blast Injury

Operational Stressors

- ▶ Sleep Deprivation
- ▶ Traumatic Stress and Situational Stressors
- ▶ Physical Work Load
- ▶ Cognitive Burden & Operational Complexity

Systems Hazards

- ▶ Laser
- ▶ Blast
- ▶ Biomechanical Insults and Stresses
- ▶ Noise





Human Dimension - A Key Concept



To prevail in a complex environment, the Army must maintain a **decisive edge in the human dimension**. We will accomplish this by **optimizing human performance**, building cohesive teams of Army Professionals.

Past

**Reacted
to ambiguity**



Future

**Improve
and Thrive
in ambiguity**



Requires investment and innovation in **education, training, and leader development**. The Army must address this challenge at the **individual, collective, and institutional levels**.





Army System for Health: Enabling Land Power Through the Human



MEDCOM PRIORITIES: Combat Casualty Care | Readiness & Health of the Force | Ready & Deployable Medical Force | Health of Families & Retirees

Performance Triad



Delivery of Health



Healthy Environments



**Enhanced
Performance &
Readiness of
the Force**

**Healthcare
To
Health**

**Enables Health
of Soldiers,
Families, and
Retirees**

Platform for Readiness

Foundation of Human Performance Optimization
Sleep, Activity, & Nutrition Enables Physical, Emotional, & Cognitive Dominance

Physical | Emotional | Social | Spiritual | Family



Human Dimension Vision and Outcomes: What are we trying to achieve?



Human Dimension Vision
Maximized individual and team performance through identification, development, and optimal integration of human capabilities.

Red font indicates direct medical S&T support

Maximized Army Professionals

- Accelerated ethical maturity and strengthened character
- Improved ethical conduct
- Accelerated inculcation of Army values
- Expanded professional certification and credentialing
- Increased propensity to serve
- Increased commitment to the profession
- Improved resource stewardship

Supporting Effort

Optimized Job Performance

- Accelerated leader development and team building
- Accelerated learning and experience
- Improved cognition: attention; problem solving; knowledge and skill retention; decision making; reasoning; learning
- Adaptive and agile mission-ready performance
- Improved social and interpersonal interaction/competency; diversity and inclusion
- Improved health/stamina
- Improved cross-cultural competence
- Improved accessions and talent utilization

Main Effort

Optimized Holistic Health and Fitness

- Increased resilience and post-traumatic growth
- Increased injury prevention
- Reduced short- and long-term disability
- Improved physical, mental, and emotional health
- Improved physical, cognitive, and social fitness baseline
- Improved stress management/adaptation
- Enhanced full lifecycle fitness assessment

Supporting Effort



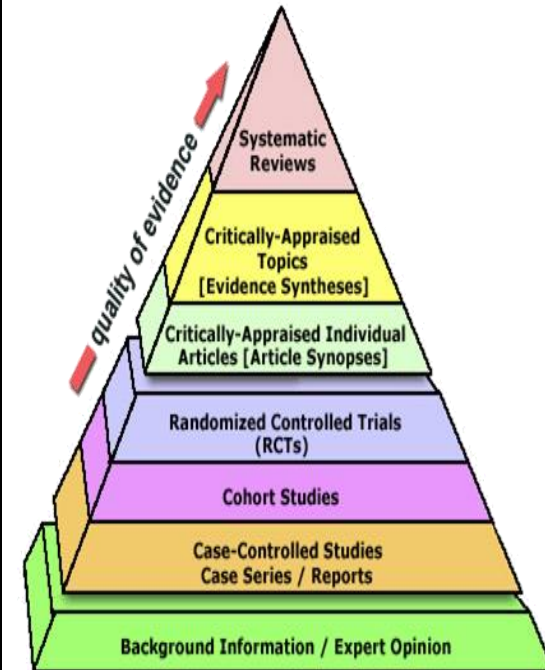


USAMRMC Medical S&T and ACQ: Quality of Evidence in Biomedical Research



Our Soldiers deserve medical information and products that have been thoroughly tested for safety and efficacy.

Grade of Recommendation	Level of Evidence	Therapy: Whether a treatment is efficacious/ effective/harmful	Therapy: Whether a drug is superior to another drug in its same class
A	1a	SR* (with homogeneity) of RCTs	SR (with homogeneity of head-to-head RCTs)
	1b	Individual RCT** (with narrow Confidence Intervals)	Within a head-to-head RCT with clinically important outcomes
	1c	All or None	
B	2a	SR (with homogeneity*) of cohort studies	Within a head-to-head RCT with validated surrogate outcomes
	2b	Individual cohort study (including low-quality RCT; e.g., <80% follow-up)	Across RCTs of different drugs vs. placebo in similar or different patients with clinically important or validated surrogate outcomes
	2c	"Outcomes" Research; Ecological studies	
	3a	SR (with homogeneity of case-control studies)	Across subgroup analyses from RCTs of different drugs vs. placebo in similar or different patients, with clinically important or validated surrogate outcome
	3b	Individual Case-Control Study	Across RCTs of different drugs vs. placebo in similar or different patients but with unvalidated surrogate outcomes
C	4	Case-series (and poor quality cohort and case-control studies)	Between non-randomised studies (observational studies and administrative database research) with clinically important outcomes
D	5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"; or non-randomised studies with unvalidated surrogate outcomes



*SR=Systematic Reviews

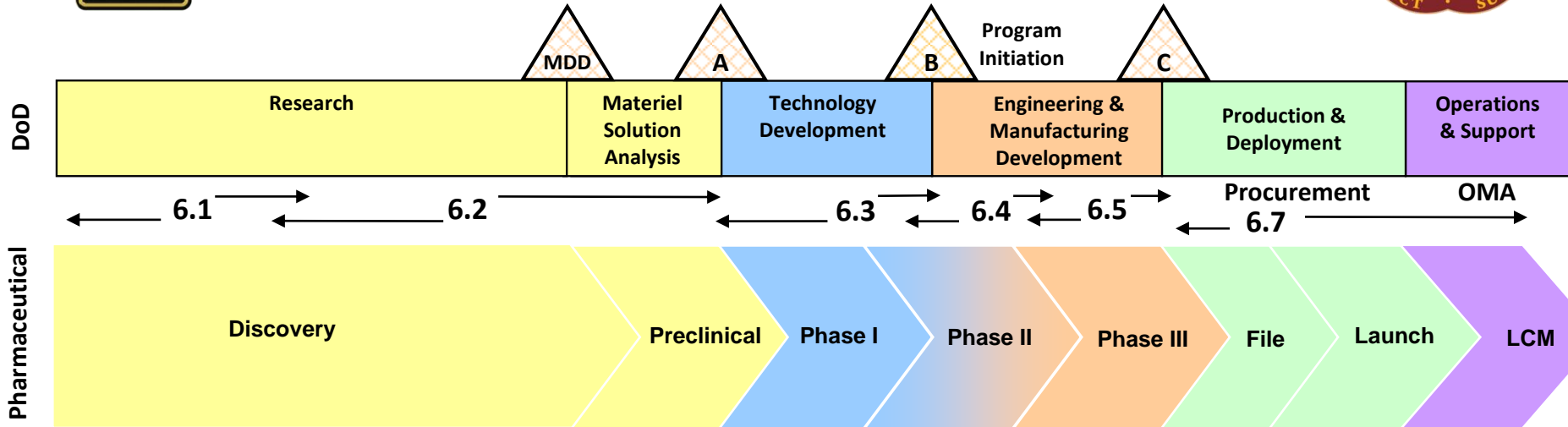
Ref: Oxford Center for Evidence-based Medicine Levels (May 2001)

**RTC=Randomized Controlled Trials

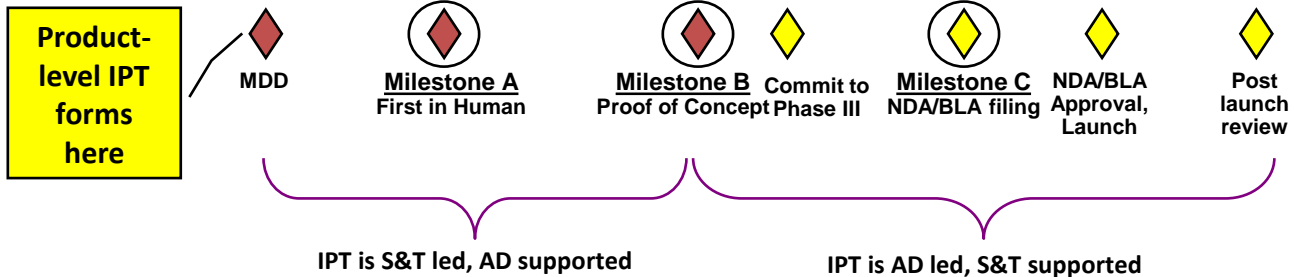




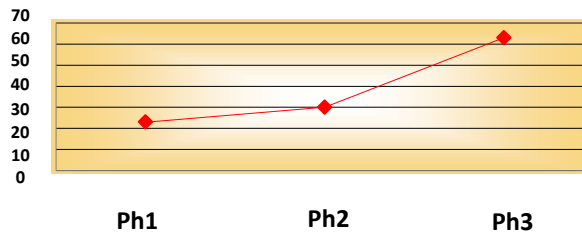
Scope of USAMRMC S&T: Basic Research Through Milestone B Transition



- No solid lines
- Requires teamwork & thought every time
- Phase I (10s of humans)
 - ▶ Safety
- Phase II (100s of humans)
 - ▶ Safety
 - ▶ Dose Ranging
 - ▶ Limited Efficacy
- Phase III (1000s of humans)
 - ▶ Efficacy
- Phase IV (Adverse Events)
 - ▶ Post Marketing Surveillance



Probability of Approval at Development Stage



- **Technology Risk**
 - ▶ Significant throughout the process
 - ▶ Technology failure is a critical cost driver
 - ▶ Investment programming must accommodate failure rate





Program Area Directorates



PA(R&T) Fort Detrick, MD

**Principal Assistant for
Research & Technology**

Dr. Frazier Glenn

Program Area Directorates (PADs) – Functions

- Manage programs; do not execute programs (do not perform research and technology)
- Fund intramural and extramural research and technology
- Responsible for both the problem set and the solution set
- Devise a research strategy (program) and fund research and technology that fit the program
- Widely networked/many meetings

Medical Training and Health Information Sciences

Dr. Janet Harris

- Medical simulation and training
- Health informatics and mobile health
- Decision support tools and physiological models

Military Infectious Diseases Research Program (MIDRP)

COL Michael Kozar

- Medical Readiness
- Vaccines
- Biotechnology
- Prophylaxis/treatment drugs
- Diagnostics/prognostics
- Vector control
- Medical C4ISR
- HIV countermeasures (congressional mandate)



Combat Casualty Care Research Program (CCCRP)

Col Todd Rasmussen

- Trauma care and resuscitation
- Traumatic brain injury care
- Blood replacement on the battlefield
- Technology to support combat medic
- Acute pain management
- Burn and acute wound management
- Combat dentistry research



Military Operational Medicine Research Program (MOMRP)

CAPT Douglas Forcino

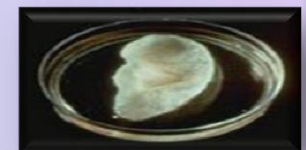
- Injury prevention and reduction
- Psychological health and resilience
- Physiological health
- Environmental health and protection



Clinical & Rehabilitative Medicine Research Program (CRM RP)

LTC Teresa Bringer

- Rehabilitation and prosthetics
- Regenerative medicine and transplants
- Restore vision
- Pain management





- *Infectious Disease Prevention and Treatment*
- *Wound Infection Prevention and Management*
- *Vector Control*
- *Diagnostics*
- *Blood Screening*



Mosquitoes and ticks transmit diseases



(A) ETEC, (B) *Shigella*, and (C) *Campylobacter* are most common agents responsible for bacterial diarrhea



Malaria parasites in red blood cell cause lysis and anemia

Diagnostics devices

Key Objectives

1. Infectious Diseases Prevention

- *Partnership opportunities for a combination ETEC/Campylobacter and/or ETEC/Shigella vaccine development*
- *Partnership opportunities to conduct post-Phase 2 clinical trials with next generation malaria prophylactic drugs*

2. Wound Infection Prevention and Management

- *Development of tools for early detection of drug-resistance organisms for better wound infections management*

3. Diagnostics

- *Development of rapid pathogen detection assays for inclusion to the Next Generation Diagnostic System (NGDS)*

4. Vector Control

- *Development of innovative technologies for vector detection and control*

5. Blood Screening

- *Development of innovative, hand-held systems to be used as a blood donor screen in urgent situations*





- *Injury Prevention and Reduction*
- *Physiological Health and Performance*
- *Environmental Health and Protection*
- *Psychological Health and Resilience*



Key Objectives

1. **Injury Prevention & Reduction**
 - *Screening tools for return-to-duty*
2. **Physiological Health & Performance**
 - *Nutritional approaches matched to specific mission requirements*
3. **Environmental Health and Protection**
 - *Microclimate heating and cooling systems*
 - *Improved physiological status monitoring and hydration status monitoring capability*
 - *Performance in extreme environments*
4. **Psychological Health & Resilience**
 - *Enhanced Service member and family psychological health & resilience*
 - *PTSD pharmaceutical development*
 - *Cognitive performance assessment and prediction*
 - *Suicide prevention strategies*





Combat Casualty Care Research Program (CCCRP)



- *Hemorrhage, Shock, and Coagulopathy of Trauma*
- *Neurotrauma and Brain Dysfunction*
- *Treatments for Extremity Trauma, Tissue Injury, Craniomaxillofacial Injury, Lung Injury, and Burns*
- *Pre-hospital Tactical Combat Casualty Care*
- *Enroute Care*



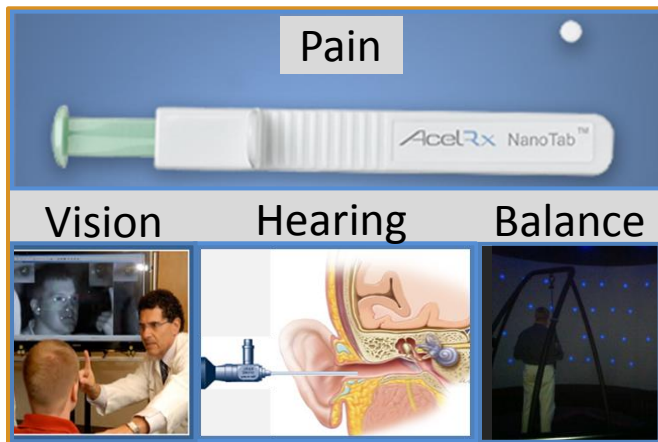
Key Objectives

1. Reduce the mortality and morbidity associated with combat-related trauma
 - *Continuum of Care*
 - *Future Operations*
2. Identify and develop medical techniques and materiel for early interventions
 - *Point of Injury*
 - *Form/Fit Factor*
3. Translate military-relevant basic and preclinical trauma research into clinical practice
 - *Facility-Based Treatment*
 - *Clinical Relevance*





- *Neuromusculoskeletal Injury (including Amputee)*
- *Regenerative Medicine and Transplants*
- *Pain Management (Acute/Chronic/Battlefield)*
- *Sensory Systems (Vision/Hearing/Balance)*



Key Objectives

1. Manage Pain

- *Battlefield*
 - *Field alternatives to IM morphine*
- *Chronic*
 - *Therapies to reduce opioid ADE*
 - *Novel analgesics*
 - *Objective diagnostics*

2. Restore Sensory Systems

- *Novel Interventions*
 - *Diagnostics*
 - *Treatments*
 - *Sensory simulation*
- *Pharmaceuticals*
 - *Mitigation and treatment*
- *Regenerative/Rehabilitation Strategies*





- *Medical Modeling, Simulation, and Training*
- *Health Information Technologies/ Informatics*



Key Objectives

1. Develop appropriate simulation systems, trainers, or educational products to address the continual need of military medical personnel to maintain a high state of readiness.
2. Research effective and efficient team communication (verbal and non-verbal), and develop and evaluate team training simulation systems. What does a future Joint En Route Training System look like?
3. Research to capture, document, and transmit bio-medical data.
4. Continue investments to investigate and improve management and movement of health data.





Laboratory Commands



USAMRIID

Ft. Detrick, MD

U.S. Army Medical Research Institute of Infectious Diseases



WRAIR

Forest Glen, MD

Walter Reed Army Institute of Research

- Armed Forces Research Institute for Medical Sciences (AFRIMS), Thailand
- U.S. Army Medical Research Unit, Europe (USAMRU-E), Germany
- U.S. Army Research Unit, Kenya (USAMRU-K)
- U.S. Army Medical Research Unit, Georgia (USAMRU-G)

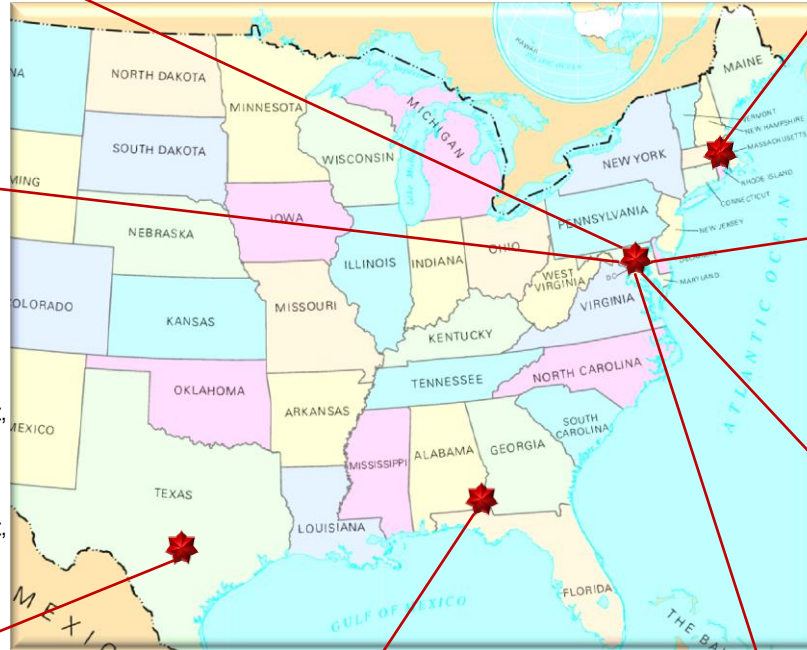


USAISR

Ft. Sam Houston, TX

U.S. Army Institute of Surgical Research

- U.S. Army Dental and Trauma Research Detachment (USADTRD), Ft. Sam Houston, TX
- U.S. Army Medical Research Detachment (USAMRD), Ft. Sam Houston, TX



USAARL
Ft. Rucker, AL
U.S. Army Aeromedical Research Laboratory



USARIEM

Natick, MA

U.S. Army Research Institute of Environmental Medicine



USAMRICD

Aberdeen PG, MD

U.S. Army Medical Research Institute of Chemical Defense



TATRC

Ft. Detrick, MD

Telemedicine and Advanced Technology Research Center

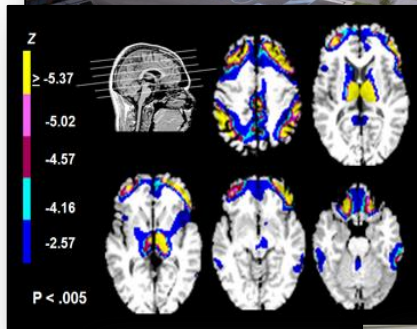


USACEHR

Ft. Detrick, MD

U.S. Army Center for Environmental Health Research





1. Competencies

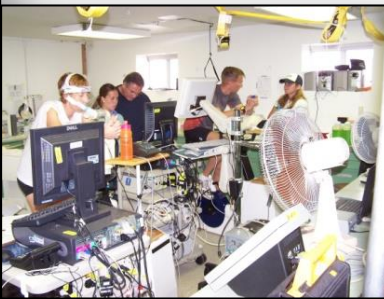
- *Infectious Diseases: Parasitic, Bacterial, Viral*
- *Vector Control*
- *TBI Neurotrauma & Brain Dysfunction*
- *Psychiatry & Clinical Psychology Disorders*
- *Cognitive Health & Performance*
- *Behavioral Health, Wellness, & Resilience*

2. Location: Silver Spring, MD

3. Unique Capabilities/Facilities

- *Pilot Bioproduction Facility*
- *Sleep laboratory*
- *Center for Military Psychiatry and Neuroscience*
- *Accession Medical Standards Analysis and Research Activity (AMSARA)*
- *OCONUS infectious disease labs in Thailand, Kenya, and Georgia, and clinical trial sites in Africa and SE Asia*
- *U.S. Army Medical Research Unit–Europe (USAMRU-E), Heidelberg, Germany – Field studies of psychological health and management practices*





1. Competencies

- *Brain Health & Performance Risk*
- *Heat, Cold, & Terrestrial Altitude*
- *Musculoskeletal Injury*
- *Nutrition & Weight Balance*
- *Warfighter Physical Performance*
- *Biophysics and Biomedical Modeling*

2. Location: Natick, MA

3. Unique Capabilities/Facilities

- *Bone Health Laboratory*
- *Center for Military Biomechanics Research*
- *Doriot Climatic Facility*
- *High-Altitude Laboratory (Pikes Peak, CO)*
- *Human Performance Laboratories*
- *Hypobaric Chambers and Hypoxia Rooms*
- *Warfighter Cognitive Performance Laboratory*





1. Competencies

- *Aircrew Health & Performance*
- *Sensory Performance, Injury & Protection*
- *En Route Care Environment*
- *Crew Survival in Military Helicopters & Combat Vehicles*

2. Location: Fort Rucker, AL

3. Unique Capabilities/Facilities

- *UH-60 Blackhawk helicopter and flight simulator fully instrumented for physiology and performance studies*
- *Human Psychophysiology, Polysomnography, and Bright Lights Testing Facility*
- *Man-Rated Multi-Axis Ride Simulator (MARS), instrumented for physiological monitoring, biomechanical measurement, and human performance assessment*
- *Instrumented Marksmanship Range*
- *Acoustic and Visual Sciences Research Laboratories, including mobile facilities for field studies*





1. Competencies

- *Traditional & Emerging Chemical Threats*
- *Biological Toxins*

2. Location: Aberdeen Proving Ground, MD

3. Unique Capabilities/Facilities

- *ADME (Absorption, Distribution, Metabolism, Excretion) Center of Excellence*
- *Chemical safety/surety/security/intel programs*
- *Training program for chemical casualty care and civilian disaster response planning*





1. Competencies

- *Bacterial Diseases*
- *Viral Diseases*
- *Biological Toxins*

2. Location: Fort Detrick, MD

3. Unique Capabilities/Facilities

- *Biological containment facilities up to Biosafety Level 4*
- *Biological Select Agents and Toxins (BSAT) program*
- *Expertise in FDA approval of medical products under the “Animal Rule”*
- *Training program for biological casualty care and civilian disaster response planning*





1. Competencies

- *Maxillofacial Trauma & Combat Dentistry*
- *Extremity Trauma*
- *Ocular Trauma*
- *Burn Injury*
- *Hemorrhage, Shock, & Coagulopathy of Trauma*
- *Pain*
- *Pre-Hospital Tactical Combat Casualty Care*
- *Critical Care Delivery*

2. Location: Fort Sam Houston, TX

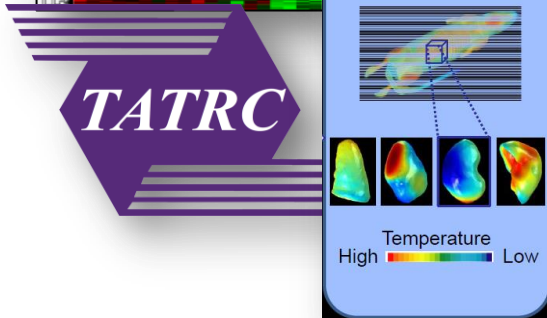
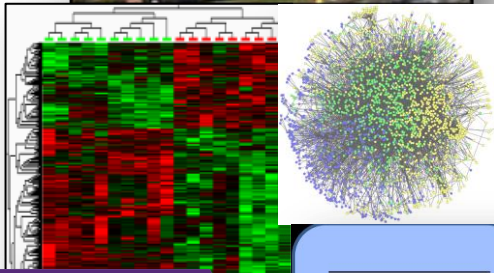
3. Unique Capabilities/Facilities

- *DoD Burn Center (patient care and research)*
- *Joint Trauma System: Data analysis of medical records and operations to promote performance improvements in combat casualty care*
- *Co-located with San Antonio Military Medical Center and Center for the Intrepid*





Additional Laboratory Capabilities



1. U.S. Army Center for Environmental Health Research (USACEHR), Fort Detrick, MD
 - *Competency*
 - *Environmental Toxicant Exposure*
 - *Unique Capabilities/Facilities*
 - *Aquaculture facility*
 - *Central USAMRMC coordinating hub for Systems Biology*
2. Telemedicine and Advanced Technology Research Center (TATRC), Fort Detrick, MD
 - *Competencies*
 - *teleHealth*
 - *Health Information Technology*
 - *Medical Simulation & Training Systems*
 - *Medical Intelligent Systems*
 - *Unique Capabilities/Facilities*
 - *Biological High Performance Computing Software Applications Institute*
 - *Medical Humanitarian Assistance/Disaster Relief Communications Support*
 - *Medical Technology Innovation Programs*





Public-Private Partnerships (PPPs)



1. PPPs are contractual agreements or voluntary, non-contractual collaborations between public and private sector entities that leverage expertise, resources, and incentives to achieve mutually agreed upon goals.
2. Benefits of PPPs
 - *Optimize both financial and research resources by providing a link to small, innovative companies, pharmaceutical companies, universities, non-profit entities, and private citizens to address military medical needs.*
 - *Potential to attract private-sector participants that may not typically seek business with USAMRMC.*
 - *Foster communication and understanding of strategic technical and business objectives of USAMRMC and partnership members.*
 - *Improve flexibility in investments, acquisition strategies, and the negotiation of intellectual property and patent rights.*
3. To address military medical needs, USAMRMC is in the process of establishing PPPs.

Example Consortia via PPPs
Center for Manufacturing Science
National Warheads and Energetics Consortium
Robotics Technology Consortium
National Small Arms Technology Consortium
Vertical Lift Consortium
Nano Valley Consortium
The Applied Nanotechnology Consortium
System of Systems Consortium (Homeland Defense)
Consortium for Energy, Environment and Demilitarization
System of Systems Consortium (Homeland Defense)





Medical Technology Enterprise Consortium (MTEC)



1. MTEC will be a consortium of industrial, academic, and other organizations operating as a 501(c)(3) non-profit corporation awarded under an Other Transaction Agreement (OTA) pursuant to 10 U.S.C. 2371
 - *A PPP aimed at establishing private shared-funding and collaboration to support military medical innovation*
 - *Enables shared funding of medical research and development for prototypes that specifically meet pre-established military medical technology objectives*
 - *OTA enables operations and relationships with MTEC not subject to the Federal Acquisitions Regulations and DoD Grant and Agreement Regulations*
 - *Allows consortium members to operate with each other with limited protection from antitrust liability*
 - *Solicitation posted 9 Feb 2015 on FedBizOpps under W81XWH-15-MTEC*

*Expected Initial Operational Capability
(enrollment of new consortium members) in 4QFY15-1QFY16*





USAMRMC - Collaborative by Nature & Necessity



SUCCESSFUL LIFECYCLE MANAGEMENT COMMAND



Defense Acquisition Regulations Directorate

INTEGRATION OF DOD AND FDA REGULATIONS

C·D·R·H



CDER

CBER



COLLABORATIVE COMMAND



Industry



Academia



Health Affairs



International





Questions?



For additional questions after the conclusion of the conference, send an email message to usarmy.detrick.medcom-usamrmc.mbx.mmpd@mail.mil

