



Medical Product Development Gaps Requiring Industry Support

MILITARY MEDICINE PARTNERSHIP DAYS
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Agenda



- Overview of USAMRMC Medical Product Development Program – Dr. Tyler Bennett and Ms. Kathleen Berst
- United States Army Medical Materiel Development Activity Gaps
 - Pharmaceutical Systems – Dr. Kendra Lawrence
 - Neurotrauma and Psychological Health – LTC Jose Manuel Pizarro
- United States Army Medical Materiel Agency Gaps – Ms. Nicolle Perez





Overview of USAMRMC Product Development Program

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Dr. Tyler Bennett
Deputy for Acquisition
United States Army Medical Materiel Agency

Ms. Kathleen Berst
Deputy for Acquisition
United States Army Medical Materiel Development Activity

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Why is Army Medicine Involved?



We select, modify, and procure commercial medical materiel solutions when appropriate or we partner to develop.

We take the lead in R&D when:

- The issue is unique to the military
- Industry/academia lack interest
- Military needs require acceleration of solution
- Directed by Congress
- Available commercial product cannot be sustained in military environment

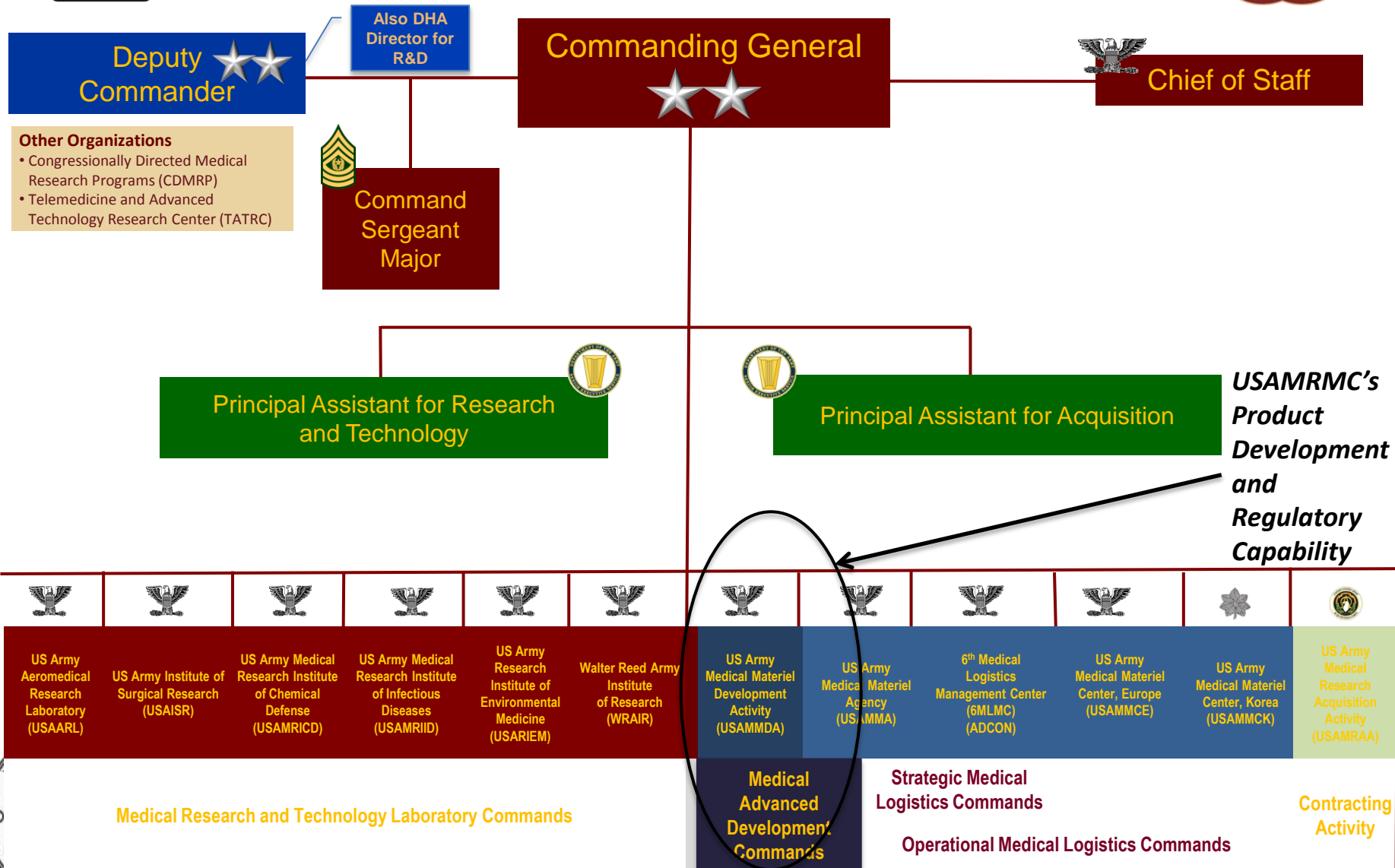




USAMRMC Organization Chart

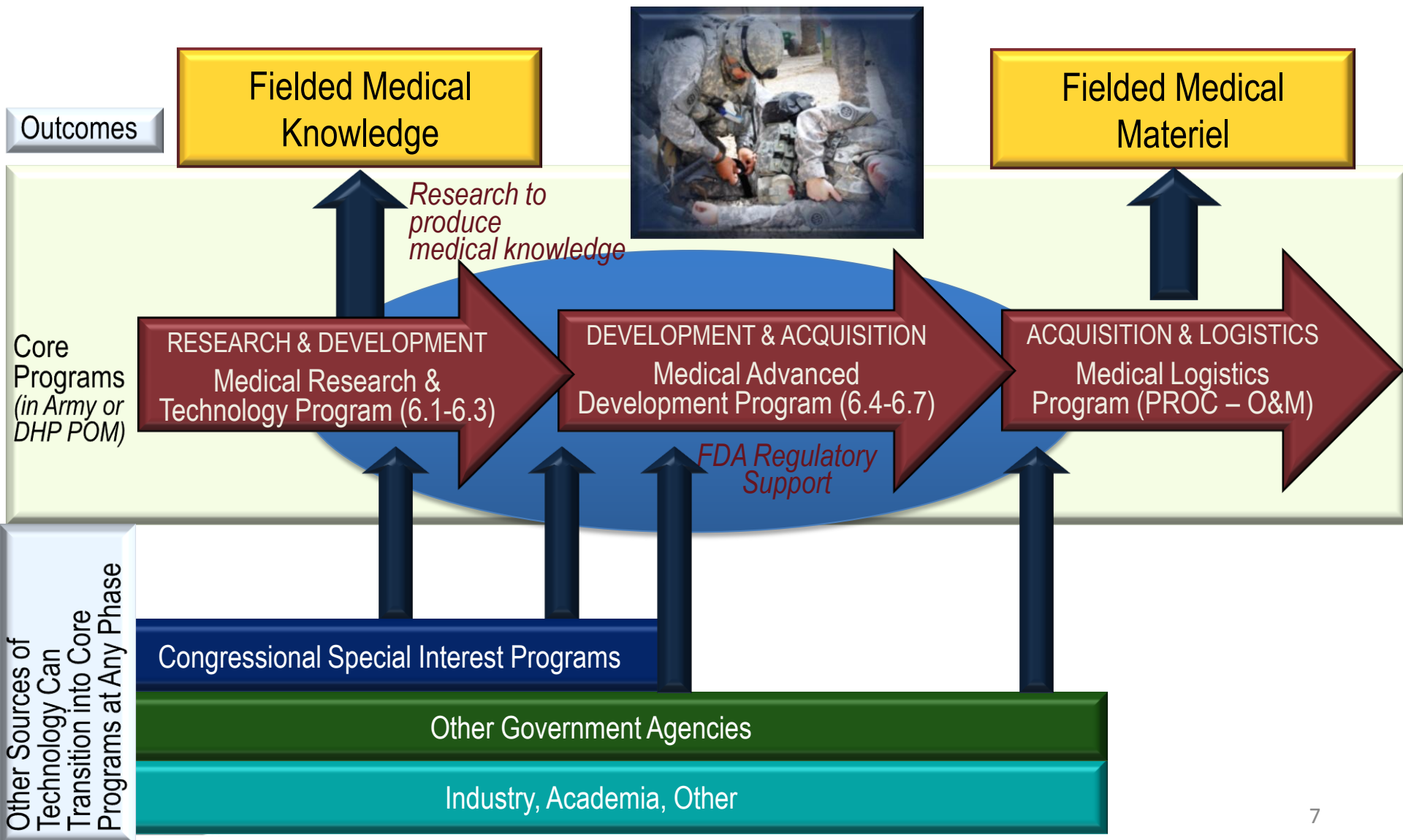
USAMRMC Actual Personnel – DEC 2016

MILITARY	CIVILIAN	CONTRACTOR	TOTAL
1064	2268	3189	6521
16%	35%	49%	100%





USAMRMC Operational Scope

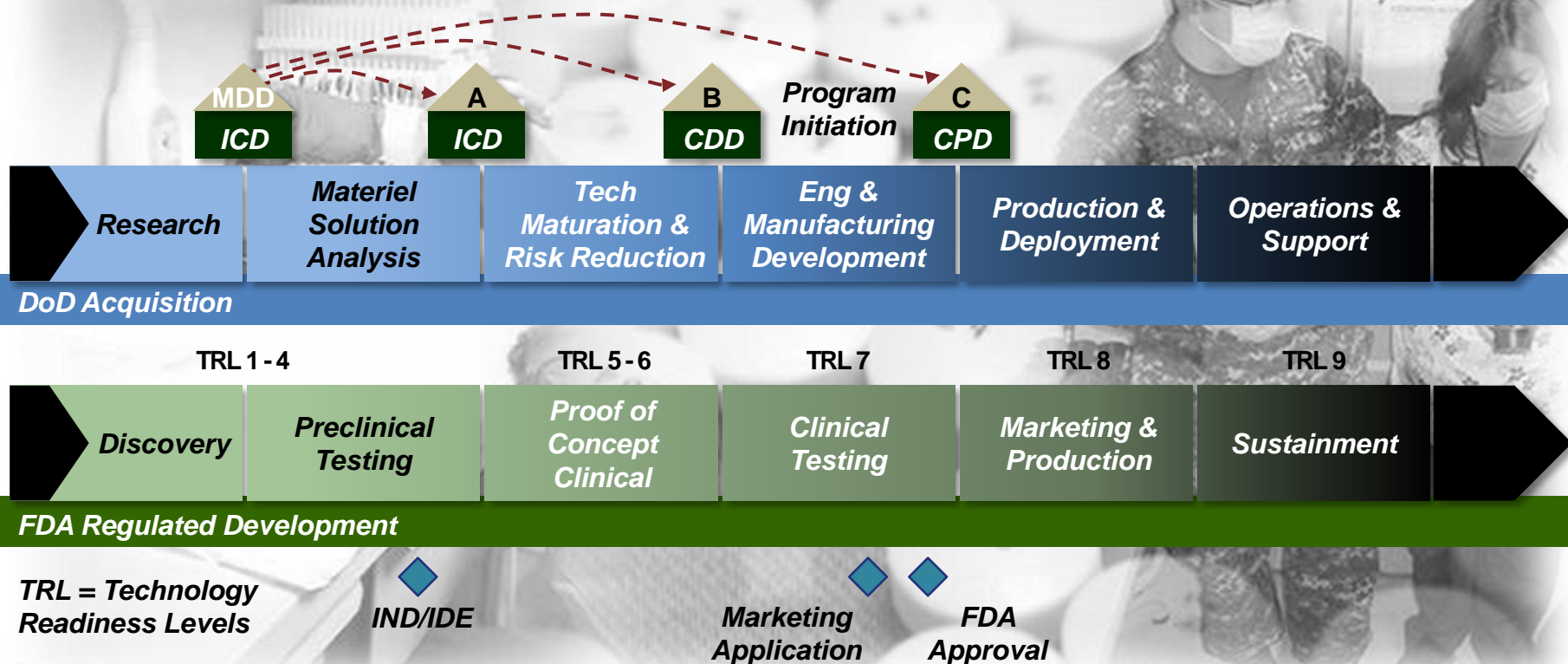




Governing Processes



Integration of DoD 5000 and FDA Regulation Process



“Translate Research Into Products”



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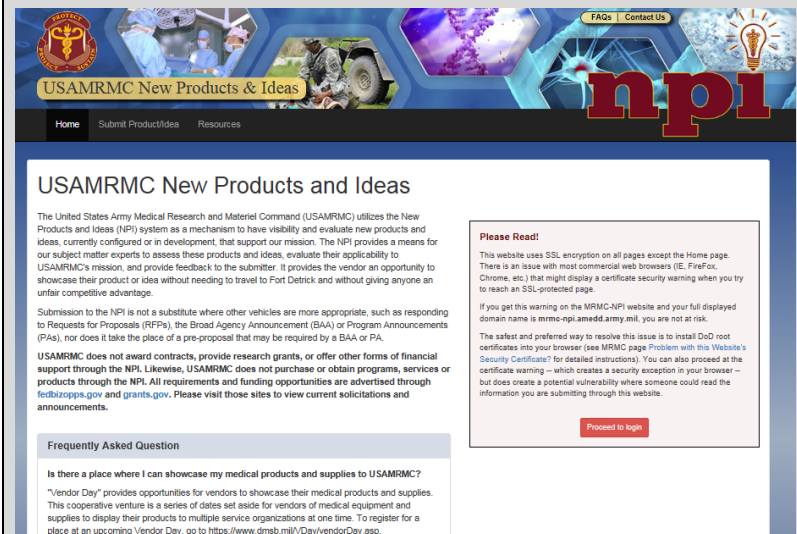


How to Work with Us



- **Commercial Off The Shelf (COTS) items**
 - General Supply Schedules (i.e. E-CAT, E-MALL, GSA Advantage)
 - Direct Contract
- **Developmental Items**
 - Cooperative Research and Development Agreement (CRADA)
 - Broad Agency Announcement (BAA)
 - Small Business Innovation Research (SBIR)
 - Small Business Technology Transfer (STTR)
 - Other Transaction Authority (OTA)
 - Direct contract

**Submit your ideas via the
“New Products & Ideas” web portal**
<http://mrmc-npi.amedd.army.mil/>



Sign up for Vendor Days

<http://www.health.mil/VendorDay>





United States Army Medical Materiel Development Activity (USAMMDA)

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Where Our Products Touch the Lives of Warfighters



Prevention

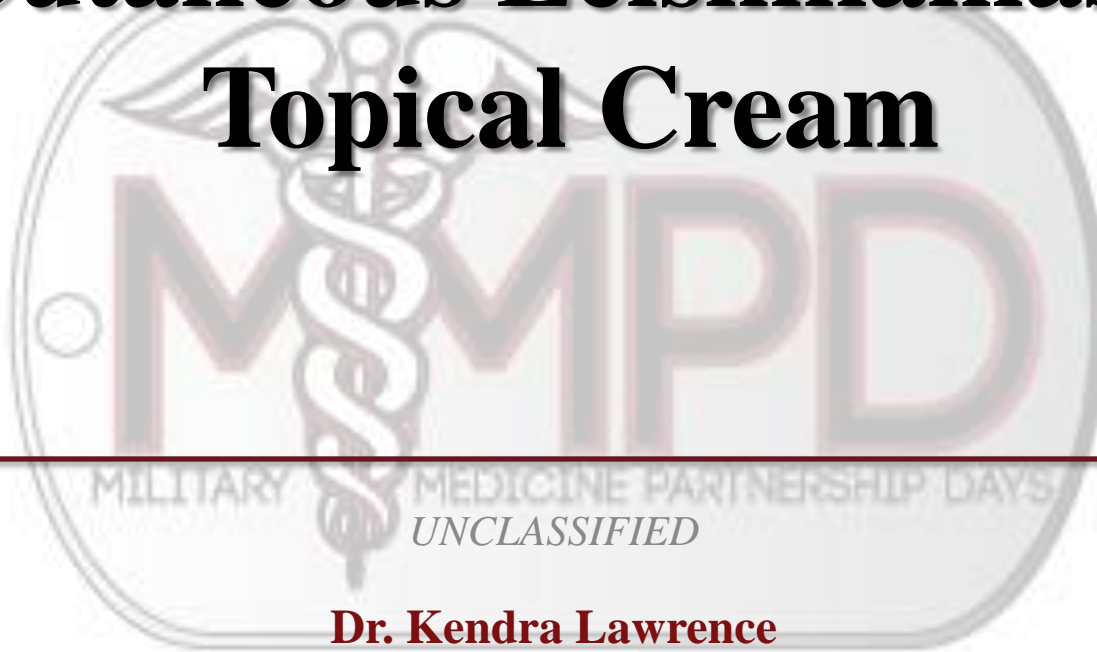
Diagnose and Treat

Rehabilitate & Restore





Cutaneous Leishmaniasis Topical Cream



Dr. Kendra Lawrence

Product Manager

Pharmaceutical Systems Project Management Office

USAMMDA

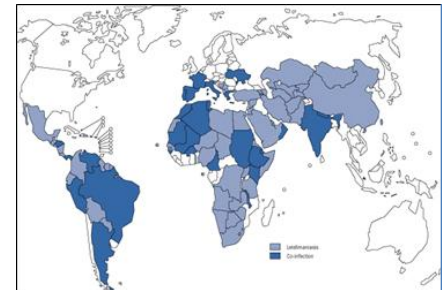
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Cutaneous Leishmaniasis (CL)



- CL is caused by *Leishmania spp.*, single-cell protozoan parasites transmitted through sand fly bites
- The WHO estimates that:
 - Over 430M people live in endemic areas
 - 12M currently infected; 700K to 1.3M new cases yearly
- Lesions typically form on the face, arms, or legs producing potentially disfiguring ulcers and scarring
- Available treatments have toxic and painful side effects, are expensive, and can be difficult to administer
 - Treatments generally last ~20 days and administered in a medical facility
 - Military patients require higher echelons of care and/or evacuation





Topical Paromomycin



- In Phase 3 clinical trials (Tunisia (2011), Panama (2016)), Topical Paromomycin demonstrated an ~80% cure rate and an excellent safety profile
- Topical, self-application (once daily x 20 days) represents a significant improvement over current standard of care
 - Facilitates immediate return to duty for deployed military
- Clinical development complete; in late-stage manufacturing
- FDA has granted Orphan Drug and Fast Track Designation
- Anticipate NDA submission in late 2018
- Topical Paromomycin will be available for licensing





Neurotrauma and Psychological Health Gaps

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LTC Jose Pizarro
Deputy Project Manager
Neurotrauma and Psychological Health Project
Management Office

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Neurotrauma & Psychological Health



- Mission: To develop suitably mature **materiel products** for the **treatment and diagnosis of Neurotrauma and Psychological Health conditions**, such as traumatic brain injury (TBI), Post-Traumatic Stress Disorder (PTSD), and suicidality.

Neurotrauma Gaps

- TBI treatments/therapies
 - Pipeline; Delivery
 - Mild TBI/Prevent PCS
- Enhanced Classifications
- Blast dose to injury
- Genetic predisposition
- Novel biomarkers for prognosis, diagnosis and treatment efficacy

Psych Health Gaps

- Treatments and preventions PTSD
 - pathophysiology of PTSD using neuroimaging, genetics/genomics, and physiological measures
- Subtypes of PTSD
 - Identification; Treatment specific
- Validated measures for symptoms and impairment in **military population**
- Suicide prevention





United States Army Medical Materiel Agency (USAMMA)

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Ms. Nicolle Perez
Biomedical Engineer
US Army Medical Materiel Agency

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Areas of Interests



- Hemorrhage and Resuscitation
- Traumatic Brain Injury (TBI) Diagnostics and Treatments
- Post Traumatic Stress Disorder (PTSD) Diagnostics and Treatments
- Ocular Salvage Devices
- Wearable Sensors
- Telehealth
- Medical Evacuation
- Reduction of Weight, Cube and Cost for Items in Medical Sets, Kits and Outfits
- Modernization of Obsolete and Discontinued Medical Equipment
- Standardization of integrated clinical technologies





Areas of Interest (cont.)



- Hemorrhage control



ResQFoam - An
Intracavitary
Noncompressible
Hemorrhage Control Agent



- Traumatic Brain Injury
Diagnostics and
Treatments



Non-invasive
Neuro-diagnostics





Areas of Interest (cont.)



- Wearable sensors



Sotera ViSi Mobile



Athena GTX WVSM

- Telehealth

- Medical evacuation



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Oxygen Generator
Field Portable





Questions?



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

